

BILINGUAL ADULT WORKBOOK

PHARMA BUSINESS ENGLISH FROM A1 TO B2

Inglés farmacéutico para el trabajo

Quality | Regulatory | Clinical | Manufacturing | Meetings

LANGUAGE FOR REGULATED WORK



PRECISE. CAUTIOUS. ACTIONABLE.

ENGLISH + ESPAÑOL

START HERE

Precise language protects the work

El lenguaje preciso protege el trabajo

Name / Nombre: _____

Function / Área: _____

Date / Fecha: _____

This workbook develops English for cross-functional pharmaceutical workplaces. It focuses on clarity, cautious interpretation, documented action and respectful challenge. All companies, products, people and data are fictional training examples.

APOYO EN ESPAÑOL
Este cuaderno desarrolla inglés para entornos farmacéuticos multifuncionales. Se centra en claridad, interpretación prudente, acciones documentadas y cuestionamiento respetuoso. Todas las empresas, productos, personas y cifras son ejemplos ficticios de capacitación.

IMPORTANT SCOPE / ALCANCE IMPORTANTE
Language training only. This workbook does not provide medical, scientific, quality, safety, legal or regulatory advice. Follow current requirements, approved procedures and qualified experts in your organisation.
Solo capacitación lingüística. Este cuaderno no ofrece asesoramiento médico, científico, de calidad, seguridad, legal ni regulatorio. Sigue los requisitos vigentes, procedimientos aprobados y especialistas cualificados de tu organización.

CONTENTS / CONTENIDOS

Pharma Language Foundations	5
Meetings, Risk and Action	13
Connect Evidence and Decisions	22
Present Complex Information Clearly	30
Grammar for Precision and Responsibility	40
Real-World Cross-Functional Scenarios	49
Confidence Through Deliberate Practice	59
Suggested Answer Key	70

HOW TO USE IT / CÓMO USARLO

1. NOTICE Read for meaning and risk.	2. CHECK Use the Spanish support.	3. PRACTISE Complete a realistic task.	4. DOCUMENT Create a workplace artefact.
1. OBSERVA Lee buscando sentido y riesgo.	2. COMPRUEBA Usa el apoyo en español.	3. PRACTICA Completa una tarea realista.	4. DOCUMENTA Crea un producto laboral.

SELF-ASSESSMENT | AUTOEVALUACIÓN

Starting point and progress

Punto de partida y progreso

✓	#	CHAPTER	CAPÍTULO
☐	1	Pharma language foundations	Fundamentos del lenguaje farmacéutico
☐	2	Meetings, risk and action	Reuniones, riesgo y acción
☐	3	Connect evidence and decisions	Conecta evidencia y decisiones
☐	4	Present complex information clearly	Presenta información compleja con claridad
☐	5	Grammar for precision and responsibility	Gramática para precisión y responsabilidad
☐	6	Real-world cross-functional scenarios	Escenarios multifuncionales reales
☐	7	Confidence through deliberate practice	Confianza mediante práctica deliberada

I CAN... / PUEDO...	NOT YET	WITH HELP	INDEPENDENT	CONFIDENT
Explain my role and current work	☐	☐	☐	☐
Distinguish facts, inference and action	☐	☐	☐	☐
Raise a quality or safety concern tactfully	☐	☐	☐	☐
Summarise a decision with owner and due date	☐	☐	☐	☐
Describe data without overclaiming	☐	☐	☐	☐
Write a clear deviation or project update	☐	☐	☐	☐
Handle a difficult question honestly	☐	☐	☐	☐
Negotiate scope, timing and responsibilities	☐	☐	☐	☐

MY COMMUNICATION RISK / MI RIESGO DE COMUNICACIÓN

RISK	OFTEN	SOMETIMES	RARELY	MY EXAMPLE
I use an acronym before defining it.	☐	☐	☐	
I report an inference as if it were a fact.	☐	☐	☐	
I use passive voice and hide the owner.	☐	☐	☐	
My update lacks a decision or next action.	☐	☐	☐	
I soften so much that urgency disappears.	☐	☐	☐	

One communication habit I will improve / Un hábito de comunicación que mejoraré

CEFR ROAD MAP | RUTA MCER

Your A1-B2 route through pharma

Tu ruta de A1 a B2 en farma

LEVEL	LANGUAGE CONTROL	PHARMA WORKPLACE TASK	APOYO EN ESPAÑOL
A1	roles, departments, routine actions, dates	Introduce your role and describe a routine task.	puestos, áreas, rutinas y fechas
A2	requests, schedules, basic process language	Request a document and confirm a deadline.	solicitudes, horarios y procesos básicos
B1	updates, reasons, contrast, meeting action	Explain a deviation update and record actions.	actualizaciones, razones y acciones
B2	qualification, uncertainty, negotiation, complex reporting	Recommend a risk-based action without overclaiming.	matiz, incertidumbre, negociación e informes

THE CROSS-FUNCTIONAL MAP / MAPA MULTIFUNCIONAL

FUNCTION	CORE QUESTION	TYPICAL COMMUNICATION
R&D / Development	What are we learning about the candidate or process?	study update, technical discussion, development plan
Clinical Operations	Is the trial being conducted and documented as planned?	site update, issue escalation, protocol discussion
Regulatory Affairs	What is required for the submission or authority interaction?	dossier plan, question response, commitment tracking
Quality Assurance	Is the quality system effective and compliant?	deviation review, CAPA, audit, change control
Quality Control	Do materials and products meet approved specifications?	test result, investigation input, release support
Manufacturing	Can the process consistently deliver the required output?	batch update, capacity, validation, transfer
Pharmacovigilance	What safety information must be evaluated and communicated?	case discussion, signal review, safety update
Supply Chain	Can the right product arrive under required conditions?	forecast, shortage, temperature excursion, logistics

GLOBAL PHARMA ENGLISH / INGLÉS FARMACÉUTICO GLOBAL

Define acronyms, state units, separate observation from interpretation, and confirm the action. These habits support understanding across functions and language backgrounds.

Define siglas, indica unidades, separa observación de interpretación y confirma la acción. Estos hábitos favorecen la comprensión entre áreas y niveles de inglés.

The functions I communicate with most / Las áreas con las que más me comunico



Pharma English: where one meeting can contain QA, QC, GMP, CAPA... and somehow lunch.

CHAPTER 01

Pharma Language Foundations

Fundamentos del lenguaje farmacéutico

Pharmaceutical communication crosses scientific, operational, quality and commercial boundaries. The first skill is not knowing every term. It is defining the right term, using it consistently and making the required action unmistakable.

APOYO EN ESPAÑOL

La comunicación farmacéutica cruza límites científicos, operativos, de calidad y comerciales. La primera habilidad no es conocer todos los términos, sino definir el término correcto, usarlo con coherencia y dejar clara la acción requerida.

YOU WILL LEARN	APRENDERÁS
1. describe functions, roles and routine responsibilities	describir áreas, puestos y responsabilidades habituales
2. use core product, quality, clinical and regulatory vocabulary	usar vocabulario básico de producto, calidad, clínica y regulación
3. write a precise role profile and handover message	escribir un perfil y un mensaje de traspaso precisos

CHAPTER 01 | A1-B1

The essential vocabulary map

Mapa de vocabulario esencial

TERM	ESPAÑOL	PLAIN MEANING	WORKPLACE EXAMPLE
candidate / compound	candidato / compuesto	substance being researched or developed	The candidate is in early development.
active pharmaceutical ingredient (API)	principio activo (API)	active substance used in a medicine	The API supplier completed the investigation.
excipient	excipiente	non-active component of a formulation	The team is assessing a new excipient.
formulation	formulación	composition and form of a product	The formulation is being optimised.
dosage form	forma farmacéutica	physical form such as a tablet or solution	The dosage form is a film-coated tablet.
batch / lot	lote	defined quantity made under specified conditions	Batch P241 is on hold.
specification	especificación	approved acceptance criteria	The result is within specification.
stability study	estudio de estabilidad	study of quality over time under defined conditions	The stability study reached month six.
shelf life	vida útil	approved period a product remains suitable under stated conditions	The current shelf life is 24 months.
protocol	protocolo	approved plan for a study or activity	The amendment updates the visit schedule.
submission / dossier	presentación / expediente	package sent to a regulatory authority	The team is preparing the quality section.
marketing authorisation / authorization	autorización de comercialización	official permission to market a medicine	The timeline assumes authorisation this year.

ACTIVITY 1: MAP TERM TO FUNCTION

ACTIVIDAD 1: RELACIONA TÉRMINO Y ÁREA

Match each item to the function most likely to lead the discussion: R&D, Clinical Operations, Regulatory, QA, QC, Manufacturing or Supply Chain. More than one function may contribute.

Relaciona cada elemento con el área que probablemente lidere la conversación. Puede participar más de un área.

1 stability study 2 authority question 3 batch record 4 site activation 5 analytical result 6 deviation 7 shipment forecast

CHAPTER 01 | A2-B1

Quality and process vocabulary

Vocabulario de calidad y procesos

TERM	ESPAÑOL	USE IT FOR	COLLOCATION
standard operating procedure (SOP)	procedimiento normalizado	approved instructions	follow / revise / approve an SOP
deviation	desviación	departure from an approved instruction or expected result	open / investigate / close a deviation
root cause	causa raíz	underlying cause supported by investigation	identify / confirm a root cause
CAPA	acción correctiva y preventiva	actions to correct and prevent recurrence	define / implement / verify CAPA
change control	control de cambios	managed evaluation of a proposed change	raise / assess / approve a change
validation	validación	documented evidence that a process or system performs as intended	execute / review a validation
qualification	cualificación	documented demonstration that equipment/facilities are fit for use	complete equipment qualification
batch record	registro de lote	documented manufacturing history	complete / review the batch record
release	liberación	formal decision that material or product may proceed	release / reject / place on hold
recall	retirada del mercado	removal of distributed product	initiate / classify / communicate a recall
audit trail	pista de auditoría	record of who changed data, what and when	review the audit trail
data integrity	integridad de datos	data that are complete, consistent and trustworthy	assess a data-integrity concern

QA IS NOT QC / QA NO ES QC

Quality Assurance focuses on the quality system and confidence that requirements will be met. Quality Control focuses on testing and decisions against specifications. Organisations may distribute responsibilities differently, so follow local role definitions.

Aseguramiento de Calidad se centra en el sistema de calidad. Control de Calidad se centra en ensayos y decisiones frente a especificaciones. Las responsabilidades concretas dependen de cada organización.

ACTIVITY 2: COMPLETE THE COLLOCATION

ACTIVIDAD 2: COMPLETA LA COMBINACIÓN

Choose the strongest verb: open, meet, identify, implement, review, release, raise or close.

Elige el verbo más adecuado.

1 _____ a deviation 2 _____ specification 3 _____ a root cause 4 _____ CAPA 5 _____ an audit trail 6 _____ a batch 7 _____ a change control 8 _____ an investigation

CHAPTER 01 | B1

Terms that must not blur

Términos que no deben confundirse

PAIR	DISTINCTION	SAFE LANGUAGE	APOYO EN ESPAÑOL
observation / interpretation	what was seen vs. what it may mean	Observed: temperature reached 10°C. Interpretation: product impact is not yet determined.	observación vs. interpretación
adverse event / adverse reaction	an event is not necessarily caused by a medicine; a reaction implies a suspected causal relationship	Report the event; do not claim causality without assessment.	evento adverso vs. reacción adversa
serious / severe	seriousness is based on defined outcome/criteria; severity describes intensity	Use the organisation's approved definitions and process.	serio/grave vs. intenso
efficacy / effectiveness	performance under defined study conditions vs. performance in usual practice	State which type of evidence you mean.	eficacia vs. efectividad
approval / authorisation	usage varies by region and context	Use the authority's and organisation's preferred term.	aprobación vs. autorización
deviation / root cause	the event is not the explanation	The investigation is open; no root cause has been confirmed.	desviación vs. causa raíz
correlation / causation	association does not by itself establish cause	The variables were associated; causality has not been established.	correlación vs. causalidad

ABBREVIATIONS / SIGLAS

FIRST USE	LATER USE	AVOID
corrective and preventive action (CAPA)	the CAPA	CAPA with no definition for a mixed audience
active pharmaceutical ingredient (API)	the API	inventing a local plural such as API's
standard operating procedure (SOP)	the SOP / SOPs	assuming the same acronym means the same thing everywhere

ACTIVITY 3: OBSERVE, INTERPRET, ACT**ACTIVIDAD 3: OBSERVA, INTERPRETA, ACTÚA**

Rewrite the vague sentence as three lines: observation, current interpretation and next action. Vague sentence: 'The shipment failed because the product is unstable.' Known facts: one logger recorded 10°C for 42 minutes; the labelled range is 2-8°C; product impact has not been assessed.

Reescribe la frase vaga en tres líneas: observación, interpretación actual y próxima acción.

CHAPTER 01 | A1-A2

Grammar for roles, routines and current work

Gramática para puestos, rutinas y trabajo actual

FORM	USE	EXAMPLE	ESPAÑOL
present simple	routine, responsibility, fact	I review change controls. The lab tests samples.	rutina, responsabilidad, hecho
present continuous	work happening now or temporarily	We are investigating a complaint this week.	trabajo actual o temporal
be responsible for + noun/-ing	state ownership	Marta is responsible for tracking commitments.	ser responsable de
work in / on / with	function / project / people or tools	I work in QA, on validation, with engineering.	trabajar en / sobre / con
present perfect	experience or result relevant now	We have completed the first review.	experiencia o resultado actual

MODEL ROLE PROFILE / PERFIL MODELO

I'm Diego Salas, a quality systems specialist. I work in Quality Assurance and support manufacturing and IT. I usually review change controls and training records. At the moment, I'm coordinating the update of three procedures. We have completed the risk assessment, and the revised drafts are under review. I'm responsible for consolidating comments and confirming the approval timeline.

APOYO EN ESPAÑOL

Soy Diego Salas, especialista en sistemas de calidad. Trabajo en Aseguramiento de Calidad y apoyo a Manufactura y TI. Normalmente reviso controles de cambios y registros de capacitación. En este momento coordino la actualización de tres procedimientos. Hemos completado la evaluación de riesgos y los borradores revisados están en revisión. Soy responsable de consolidar comentarios y confirmar el plazo de aprobación.

ACTIVITY 4: CHOOSE THE TENSE

ACTIVIDAD 4: ELIGE EL TIEMPO

Complete with the present simple, present continuous or present perfect.
Completa con presente simple, presente continuo o presente perfecto.

- 1 QC normally _____ (test) incoming material.
- 2 We _____ (review) the deviation this week.
- 3 The team _____ already _____ (complete) the initial assessment.
- 4 I _____ (work) with Regulatory on the response today.
- 5 Our group _____ (maintain) the training system.

CHAPTER 01 | PRODUCE

Writing practice: profile and handover

Práctica escrita: perfil y traspaso

TASK A: WRITE YOUR PHARMA ROLE PROFILE

TAREA A: ESCRIBE TU PERFIL FARMACÉUTICO

Write 90-120 words. Include function, routine responsibilities, current work, key partners and one result. If you are entering the industry, describe a target role and transferable skills.

Escribe 90-120 palabras. Incluye área, responsabilidades habituales, trabajo actual, colaboradores clave y un resultado. Si deseas entrar al sector, describe un puesto objetivo y habilidades transferibles.

TASK B: WRITE A PRECISE HANDOVER**TAREA B: ESCRIBE UN TRASPASO PRECISO**

Write 100-130 words for a colleague taking over your task. Separate completed work, open points, risk, owner, deadline and where the approved records are stored. Do not include confidential real data.

Escribe 100-130 palabras para un colega que asumirá tu tarea. Separa trabajo completado, puntos abiertos, riesgo, responsable, fecha límite y ubicación de los registros aprobados. No incluyas datos confidenciales reales.



The agenda said 'quick quality update.' The deviation brought a 47-slide backstory.

CHAPTER 02

Meetings, Risk and Action

Reuniones, riesgo y acción

A useful pharma meeting separates verified facts, current assessment, decisions and actions. Participants need language that is concise enough for time pressure and careful enough for quality, safety and regulatory contexts.

APOYO EN ESPAÑOL

Una reunión farmacéutica útil separa hechos verificados, evaluación actual, decisiones y acciones. Los participantes necesitan un lenguaje conciso para la presión de tiempo y prudente para contextos de calidad, seguridad y regulación.

YOU WILL LEARN	APRENDERÁS
1. use vocabulary for cross-functional and quality meetings	usar vocabulario para reuniones multifuncionales y de calidad
2. clarify, challenge and escalate without blame	aclarar, cuestionar y escalar sin culpar
3. document decisions, owners, deadlines and unresolved risks	documentar decisiones, responsables, plazos y riesgos pendientes

CHAPTER 02 | A2-B1

Meeting types and decision language

Tipos de reunión y lenguaje de decisión

MEETING	PURPOSE	KEY OUTPUT	ESPAÑOL
project team meeting	coordinate scope, timing, dependencies and risks	actions and updated plan	reunión de proyecto
quality review	review quality signals, deviations, trends and system performance	decision, escalation or follow-up	revisión de calidad
change-control meeting	assess impact and readiness for a proposed change	approval path and conditions	reunión de control de cambios
safety review	review safety information through the approved process	assessment actions and documented decisions	revisión de seguridad
clinical team meeting	coordinate trial conduct, sites, data and issues	study actions and escalation	reunión del equipo clínico
inspection-readiness meeting	check records, evidence and responsibilities	gap list and remediation plan	reunión de preparación para inspección
S&OP / supply review	align demand, supply, inventory and constraints	agreed forecast and mitigation	revisión de demanda y suministro

TERM	MEANING	USEFUL COLLOCATION
quorum	minimum participation needed for a valid decision	confirm that we have a quorum
decision criterion	condition used to choose or approve	agree the decision criteria
action owner	person accountable for completion	name / confirm the action owner
due date	agreed completion date	set / move / meet a due date
dependency	work or event required before another action	identify a dependency
open point	question or item not yet resolved	track / close an open point
escalation	raising an issue to the appropriate level or process	trigger / document an escalation
rationale	documented reason for a decision	record the rationale

ACTIVITY 1: WHICH MEETING?

ACTIVIDAD 1: ¿QUÉ REUNIÓN?

Choose the best meeting type for each need. Explain what written output should follow.

Elige el tipo de reunión adecuado para cada necesidad y explica qué producto escrito debe resultar.

- 1 A new packaging line may affect validated processes.
- 2 Several product complaints show a similar pattern.
- 3 One region forecasts a temporary shortage.
- 4 Trial sites are using different versions of a worksheet.
- 5 Teams need to locate evidence before an authority inspection.

CHAPTER 02 | B1-B2

Speak clearly when the risk is unclear

Habla con claridad cuando el riesgo no está claro

FUNCTION	TOO VAGUE OR BLUNT	PROFESSIONAL LANGUAGE	ESPAÑOL
state a fact	There was a problem.	One logger recorded 10°C for 42 minutes.	indicar un hecho
state uncertainty	It is probably fine.	Product impact has not yet been determined.	indicar incertidumbre
clarify	What do you mean?	When you say 'complete', do you mean executed, reviewed or approved?	aclarar
challenge	That conclusion is wrong.	What evidence supports that conclusion?	cuestionar
raise concern	I don't like this.	I have a concern about the missing audit-trail review.	plantear una inquietud
escalate	Tell senior management.	This meets the agreed escalation criterion; I recommend notifying the quality lead now.	escalar
request action	Fix it quickly.	Could Engineering confirm the equipment status by 14:00 UTC?	solicitar acción
summarise	We discussed everything.	We confirmed two facts, left impact open and assigned three actions.	resumir

MODALS AND STRENGTH / MODALES Y FUERZA

FORM	COMMUNICATIVE FORCE	EXAMPLE
could	option or polite proposal	We could quarantine the remaining units while the assessment is completed.
should	recommendation or expected action	The team should review the original record.
must / have to	strong obligation; use only with a clear basis	The response must follow the approved procedure.
may / might	possibility, not conclusion	The excursion may affect the shipment timeline.
cannot yet	current evidence is insufficient	We cannot yet confirm product impact.
need to	necessary next step	We need to verify the calibration status.

ACTIVITY 2: SET THE RIGHT STRENGTH**ACTIVIDAD 2: AJUSTA LA FUERZA**

Rewrite each statement so certainty and urgency match the evidence.

Reescribe cada afirmación para que la certeza y la urgencia coincidan con la evidencia.

- 1 The batch is definitely unusable. (Impact not assessed.)
- 2 Maybe someone can look at the alarm. (Potentially critical alarm; immediate review required by local process.)
- 3 Quality must approve it today. (No documented deadline.)
- 4 The result proves the new process is better. (One small engineering run.)

CHAPTER 02 | MODEL

A quality meeting in action

Una reunión de calidad en acción

FICTIONAL TRAINING DIALOGUE / DIÁLOGO FICTICIO

Lena (chair): Our objective is to agree immediate controls and investigation actions for deviation Q-118. First, the verified facts. Sam?

Sam (Manufacturing): During line clearance, an operator found one unlabelled component tray beside the packaging line. Production had stopped, and no component from that tray had been used. The tray was moved to the controlled hold area.

Ravi (QC): Do we know when the tray entered the area?

Sam: Not yet. We are reviewing the access record and camera log.

Marta (QA): I want to separate the observation from the impact assessment. The observation is confirmed. Product impact is still open because reconciliation is incomplete.

Lena: Agreed. What immediate controls are in place?

Sam: The line remains stopped, the affected materials are on hold and the area has been secured.

Marta: I recommend completing reconciliation before any restart decision. We also need the tray identity, access timeline and training record.

Lena: Let me summarise. No restart decision today. Sam owns reconciliation by 16:00. Ravi will verify component identity by noon. Marta will review the evidence and document the impact assessment tomorrow. The current risk remains open. Is that accurate?

All: Yes.

APOYO EN ESPAÑOL

Lena (facilitadora): Nuestro objetivo es acordar controles inmediatos y acciones de investigación para la desviación Q-118. Primero, los hechos verificados. Sam.

Sam (Manufactura): Durante la limpieza de línea, un operador encontró una bandeja de componentes sin etiqueta junto a la línea de envasado. La producción estaba detenida y no se había usado ningún componente de esa bandeja. Se trasladó al área controlada de retención.

Ravi (QC): ¿Sabemos cuándo entró la bandeja al área?

Sam: Todavía no. Revisamos el registro de acceso y la cámara.

Marta (QA): Quiero separar la observación de la evaluación de impacto. La observación está confirmada. El impacto sigue abierto porque la conciliación no está completa.

Lena: De acuerdo. ¿Qué controles inmediatos están activos?

Sam: La línea sigue detenida, los materiales afectados están retenidos y el área está asegurada.

Marta: Recomendando completar la conciliación antes de decidir el reinicio. También necesitamos identidad de la bandeja, cronología de acceso y registro de capacitación.

Lena: Resumen. Hoy no se decide el reinicio. Sam completa la conciliación antes de las 16:00. Ravi verifica la identidad antes del mediodía. Marta revisa la evidencia y documenta el impacto mañana. El riesgo sigue abierto. ¿Es correcto?

Todos: Sí.

ACTIVITY 3: AUDIT THE MEETING**ACTIVIDAD 3: AUDITA LA REUNIÓN**

Identify the objective, verified observation, unknown information, immediate controls, decision not taken, three actions and the open risk.

Identifica el objetivo, la observación verificada, lo desconocido, controles inmediatos, decisión no tomada, tres acciones y riesgo abierto.

CHAPTER 02 | DOCUMENT

Minutes that another person can act on

Acta que otra persona puede ejecutar

SECTION	QUESTION TO ANSWER	EXAMPLE
objective	Why did we meet?	Agree immediate controls and investigation actions.
facts	What has been verified?	One unlabelled tray was found; no use has been identified.
assessment	What is the current interpretation?	Impact remains open pending reconciliation.
decision	What was agreed or not agreed?	No restart decision was taken.
action	Who will do what by when?	Sam: complete reconciliation by 16:00.
escalation	What requires attention outside the meeting?	Notify the quality lead if reconciliation is incomplete.
record	Where is the controlled evidence?	Deviation record Q-118 and linked attachments.

ACTIVITY 4: COMPLETE THE MINUTES

ACTIVIDAD 4: COMPLETA EL ACTA

Use the model dialogue to complete the record. Write 'not yet determined' where evidence is missing; do not invent facts.

Usa el diálogo modelo para completar el registro. Escribe 'aún no determinado' cuando falte evidencia; no inventes hechos.

ITEM	DECISION / ACTION	OWNER	DUE	STATUS
Reconciliation				
Tray identity				
Impact assessment				
Restart				

Rationale and open risk / Justificación y riesgo abierto

CHAPTER 02 | PRODUCE

Meeting simulation: temperature excursion

Simulación: excursión de temperatura

FICTIONAL BRIEF / CASO FICTICIO

A sealed shipment labelled for 2-8°C arrived with one logger showing 9.6°C for 55 minutes. A second logger stayed within range. The outer packaging is intact. The shipment is in controlled hold. Logger placement, calibration status and route conditions are not yet verified. Your task is communication practice, not a disposition decision.

Un envío sellado rotulado para 2-8°C llegó con un registrador que muestra 9,6°C durante 55 minutos. Otro registrador permaneció dentro del rango. El embalaje exterior está intacto. El envío está retenido. Aún no se verifican posición de los registradores, calibración ni condiciones de ruta. La tarea es práctica de comunicación, no una decisión de disposición.

TASK A: RUN A 12-MINUTE MEETING**TAREA A: REALIZA UNA REUNIÓN DE 12 MINUTOS**

Roles: Supply Chain, QA, temperature specialist and meeting chair. State facts, list unknowns, agree immediate communication and evidence-gathering actions, name owners and deadlines, and state which decision is outside the group's scope.

Roles: Cadena de Suministro, QA, especialista de temperatura y facilitador. Indica hechos, incógnitas, acciones inmediatas de comunicación y evidencia, responsables, plazos y la decisión fuera del alcance.

My role, facts, questions, limits and useful phrases / Mi rol, hechos, preguntas, límites y frases

TASK B: WRITE THE FOLLOW-UP

TAREA B: ESCRIBE EL SEGUIMIENTO

Write 140-180 words. Include status, verified facts, unknowns, immediate control, actions in owner-deadline format and the next decision point. Do not state product impact as a fact.

Escribe 140-180 palabras. Incluye estado, hechos verificados, incógnitas, control inmediato, acciones con responsable y plazo, y próximo punto de decisión. No presentes el impacto como hecho.



The data were clear. Then 'however' entered the room wearing safety goggles.

CHAPTER 03

Connect Evidence and Decisions

Conecta evidencia y decisiones

Connectors reveal the logic of a message. In pharma communication, that logic must distinguish addition from contrast, chronology from cause, evidence from conclusion and condition from commitment.

APOYO EN ESPAÑOL

Los conectores revelan la lógica de un mensaje. En comunicación farmacéutica, esa lógica debe distinguir adición de contraste, cronología de causa, evidencia de conclusión y condición de compromiso.

YOU WILL LEARN	APRENDERÁS
1. choose conjunctions and transitions by logical function	elegir conjunciones y transiciones según su función lógica
2. avoid accidental causal or certainty claims	evitar afirmaciones causales o de certeza accidentales
3. write a coherent deviation or project update	escribir una actualización coherente de desviación o proyecto

CHAPTER 03 | B1-B2

The connector control panel

Panel de control de conectores

LOGIC	CONJUNCTION	SENTENCE CONNECTOR	PHARMA EXAMPLE	ESPAÑOL
addition	and	also, in addition, furthermore	The assay met acceptance criteria. In addition, the audit trail was complete.	adición
contrast	but, although, whereas	however, nevertheless, by contrast	The alarm was brief; however, the event requires review.	contraste
cause	because, since	because of this, owing to	The run stopped because the pressure exceeded the alert limit.	causa
result	so	therefore, consequently, as a result	A required field was blank; therefore, the form was returned.	resultado
condition	if, unless, provided that	subject to, on condition that	The transfer can begin if training is complete.	condición
sequence	before, after, while	first, next, subsequently, finally	First, verify the record. Next, assess impact.	secuencia
example	such as	for example, specifically	For example, two sites used an obsolete template.	ejemplo
summary	-	overall, in summary, to conclude	Overall, the pilot met the operational target.	resumen

TIME IS NOT CAUSE / TIEMPO NO ES CAUSA

'After the filter was changed, the result improved' states chronology. 'Because the filter was changed, the result improved' states cause. Use causal language only when the evidence supports it.

'Después de cambiar el filtro, el resultado mejoró' indica cronología. 'Como se cambió el filtro, el resultado mejoró' indica causa. Usa lenguaje causal solo cuando lo respalde la evidencia.

ACTIVITY 1: NAME THE LOGIC

ACTIVIDAD 1: NOMBRA LA LÓGICA

Label each link: addition, contrast, cause, result, condition, sequence, example or summary.
Clasifica cada relación.

- 1 The sample was tested twice; however, the discrepancy remained.
- 2 The document can be approved provided that the reference is corrected.
- 3 First, confirm the method version. Next, review the raw data.
- 4 One field was missing, so the record was returned.
- 5 Several controls were effective; for example, access was restricted immediately.

CHAPTER 03 | GRAMMAR

Punctuation and cautious conclusions

Puntuación y conclusiones prudentes

PATTERN	CORRECT EXAMPLE	COMMON ERROR
clause, but clause	The test passed, but the audit trail was incomplete.	missing comma before two full clauses
sentence. However, sentence.	The test passed. However, the review remains open.	comma splice: passed, however review...
sentence; therefore, sentence.	The field was blank; therefore, the form was returned.	using therefore like a coordinating conjunction
Although clause, clause	Although the result met specification, the discrepancy was investigated.	Although...but in the same structure
Despite + noun/-ing	Despite meeting specification, the discrepancy was investigated.	Despite the result met...

FROM EVIDENCE TO CLAIM / DE EVIDENCIA A AFIRMACIÓN

STRENGTH	LANGUAGE	EXAMPLE
observation	shows, records, was observed	The logger recorded a maximum of 9.6°C.
limited interpretation	suggests, may indicate, is consistent with	The pattern may indicate intermittent contact.
uncertainty	cannot yet determine, remains unclear	We cannot yet determine the duration of exposure.
supported conclusion	supports the conclusion that	The complete reconciliation supports the conclusion that no units are missing.
action implication	therefore, based on this assessment	Based on the assessment, the team recommends additional monitoring.

ACTIVITY 2: REPAIR THE LOGIC**ACTIVIDAD 2: REPARA LA LÓGICA**

Correct the connector, punctuation or claim strength.

Corrige el conector, la puntuación o la fuerza de la afirmación.

- 1 The alarm occurred after maintenance, therefore maintenance caused it.
- 2 Although the sample met specification but the investigation remained open.
- 3 The audit trail was reviewed, however two entries were not explained.
- 4 The first run was faster. Consequently, the new method is always superior.
- 5 Despite the form was incomplete, it was approved.

CHAPTER 03 | MODEL

Model: a coherent deviation update

Modelo: actualización coherente de desviación

FICTIONAL TRAINING EXAMPLE / EJEMPLO FICTICIO

Subject: Status update - deviation Q-204 / label reconciliation

On 7 September, final reconciliation identified a difference of two labels between the electronic count and the physical return. Production was stopped, and all finished units from the affected period were placed on hold.

First, the team verified the electronic entries and repeated the physical count. The physical count was confirmed; however, one manual entry had been transcribed incorrectly. In addition, camera review showed that two damaged labels had been destroyed in line with the local procedure, but the destruction had not been entered in the electronic record.

The evidence explains the count difference. Nevertheless, the documentation failure remains a quality-system concern. No root cause has yet been approved.

Therefore, the current actions are to complete the impact assessment, investigate why the entry was missed and assess whether similar records are affected. QA owns the assessment by 10 September; Manufacturing owns the interview and record review by 9 September. Batch disposition remains outside the scope of this update.

APOYO EN ESPAÑOL

Asunto: Actualización - desviación Q-204 / conciliación de etiquetas

El 7 de septiembre, la conciliación final identificó una diferencia de dos etiquetas entre el conteo electrónico y la devolución física. Se detuvo la producción y se retuvieron todas las unidades terminadas del período afectado.

Primero, el equipo verificó los registros electrónicos y repitió el conteo físico. Se confirmó el conteo físico; sin embargo, un registro manual se había transcrito incorrectamente. Además, la cámara mostró que dos etiquetas dañadas se destruyeron según el procedimiento local, pero la destrucción no se registró en el sistema.

La evidencia explica la diferencia. No obstante, la falla documental sigue siendo una inquietud del sistema de calidad. Aún no se ha aprobado una causa raíz.

Por lo tanto, las acciones actuales son completar la evaluación de impacto, investigar por qué se omitió el registro y evaluar si existen registros similares. QA es responsable de la evaluación antes del 10 de septiembre; Manufactura, de la entrevista y revisión antes del 9. La disposición del lote queda fuera del alcance de esta actualización.

ACTIVITY 3: TRACE THE LOGIC

ACTIVIDAD 3: SIGUE LA LÓGICA

Mark one sequence link, two contrasts, one addition, one result, one limitation and every owner-deadline pair. Then explain why 'batch disposition remains outside scope' is important.

Marca secuencia, contrastes, adición, resultado, limitación y pares responsable-plazo. Explica por qué importa el límite de alcance.

CHAPTER 03 | PRACTISE

Connector clinic

Clínica de conectores

ACTIVITY 4: COMBINE WITHOUT OVERCLAIMING

ACTIVIDAD 4: COMBINA SIN EXAGERAR

Combine each set twice: first to show chronology, then to show only the strongest relationship supported by the facts.

Combina cada grupo dos veces: primero para mostrar cronología y luego la relación más sólida respaldada por los hechos.

A Maintenance ended at 09:00. The alarm occurred at 09:12. Cause is unknown.

B Three sites received training. Query errors decreased at those sites. Other process changes also occurred.

C The supplier changed packaging. Damage complaints fell. The sample is small.

D The method met system-suitability criteria. One unexplained audit-trail entry remains.

CONNECTOR CHECK / CONTROL DE CONECTORES

☐ The connector matches the intended logic. ☐ Chronology is not presented as cause. ☐ 'However' and 'therefore' are punctuated correctly. ☐ The conclusion is no stronger than the evidence. ☐ Limitations remain visible.

☐ El conector coincide con la lógica. ☐ La cronología no se presenta como causa. ☐ La puntuación es correcta. ☐ La conclusión no supera la evidencia. ☐ Las limitaciones siguen visibles.

CHAPTER 03 | PRODUCE

Writing practice: documented update

Práctica escrita: actualización documentada

FICTIONAL NOTES / NOTAS FICTICIAS

Analytical transfer T-77: receiving lab trained 4 May; first comparative run 6 May; one result outside the agreed transfer criterion; both labs confirmed correct method version; reagent lot differs; repeat testing has not been authorised; investigation owner: receiving lab; technical review due 8 May; transfer decision after review.

Transferencia analítica T-77: laboratorio receptor capacitado el 4 de mayo; primera corrida comparativa el 6; un resultado fuera del criterio acordado; ambos laboratorios confirmaron versión correcta; el lote de reactivo difiere; no se ha autorizado repetir el ensayo; investigación: laboratorio receptor; revisión técnica antes del 8; decisión después de la revisión.

TASK: WRITE A 180-220 WORD UPDATE

TAREA: ESCRIBE UNA ACTUALIZACIÓN DE 180-220 PALABRAS

Use headings or short paragraphs for status, verified facts, unknowns, current controls, actions and next decision. Use at least six purposeful connectors and two cautious claims.

Usa subtítulos o párrafos breves para estado, hechos, incógnitas, controles, acciones y próxima decisión. Usa al menos seis conectores y dos afirmaciones prudentes.



Slide 38: because apparently 'one key message' was too experimental.

CHAPTER 04

Present Complex Information Clearly

Presenta información compleja con claridad

A pharma presentation often serves several audiences at once. Good presenters decide what each audience needs, distinguish data from interpretation and guide the room toward a defined decision or next action.

APOYO EN ESPAÑOL

Una presentación farmacéutica suele servir a varios públicos a la vez. Un buen presentador decide qué necesita cada público, distingue datos de interpretación y guía a la sala hacia una decisión o acción definida.

YOU WILL LEARN	APRENDERÁS
1. adapt detail to scientific, quality, regulatory and executive audiences	adaptar el detalle a públicos científicos, de calidad, regulatorios y ejecutivos
2. describe data, uncertainty and limits accurately	describir datos, incertidumbre y límites con precisión
3. plan a concise evidence-to-decision presentation	planificar una presentación concisa de evidencia a decisión

CHAPTER 04 | B1-B2

One topic, four audiences

Un tema, cuatro públicos

AUDIENCE	THEY MAY NEED	LANGUAGE CHOICE	QUESTION TO ANTICIPATE
technical specialists	method, assumptions, variability, limitations	precise terms and enough methodological detail	How was this measured?
Quality / Regulatory	traceability, requirements, risk, rationale, commitments	controlled terms and explicit evidence boundaries	What is the documented basis?
operations / supply	timing, capacity, dependencies and mitigation	concrete actions, units, owners and dates	What changes in the plan?
executive decision-makers	business impact, major risk, options and decision	plain language, headline evidence, clear ask	What decision is needed today?
mixed external audience	shared context without confidential detail	define acronyms and avoid local shorthand	What can be concluded from these data?

SIGNPOSTING / SEÑALIZACIÓN

MOVE	USEFUL LANGUAGE	ESPAÑOL
purpose	Today I will explain the evidence, remaining risk and decision required.	Hoy explicaré la evidencia, el riesgo pendiente y la decisión requerida.
scope	This presentation covers operational performance; it does not assess clinical benefit.	Esta presentación cubre desempeño operativo; no evalúa beneficio clínico.
road map	I will cover the context, three findings and our recommendation.	Trataré el contexto, tres hallazgos y la recomendación.
transition	Let's turn from the observed result to the impact assessment.	Pasemos del resultado observado a la evaluación de impacto.
emphasis	The key point is that the evidence is incomplete.	El punto clave es que la evidencia está incompleta.
limit	These data describe one pilot and should not be generalised.	Estos datos describen un piloto y no deben generalizarse.
ask	I am requesting approval to continue the pilot under the stated controls.	Solicito aprobación para continuar el piloto con los controles indicados.

ACTIVITY 1: CHANGE THE AUDIENCE**ACTIVIDAD 1: CAMBIA EL PÚBLICO**

Explain this finding in two ways: to a technical team and to an executive committee. Finding: 'Three of 24 records required manual correction; all corrections were traceable and reviewed.'

Explica el hallazgo de dos maneras: para un equipo técnico y para un comité ejecutivo.

CHAPTER 04 | B1-B2

Describe numbers and uncertainty

Describe cifras e incertidumbre

LANGUAGE	MEANING	EXAMPLE
increase by	amount of change	Review time increased by two days.
increase to	final value	Review time increased to seven days.
from...to	starting and final values	Queries fell from 18 to 11.
percentage points	difference between two percentages	Completion rose from 80% to 88%, an increase of eight percentage points.
approximately / roughly	rounded value	Approximately one third of actions were overdue.
range	lowest to highest values	The site range was 4-11 days.
median / mean	different measures of centre	State which measure is shown; do not use them interchangeably.
n =	number included in the analysis	The pilot included 12 shipments (n = 12).

SAFE CLAIM LADDER / ESCALA DE AFIRMACIONES

EVIDENCE SITUATION	APPROPRIATE LANGUAGE	AVOID
descriptive pilot data	In this pilot, median review time fell by two days.	The process is proven to be better.
possible pattern	The pattern may indicate a training effect.	Training caused the improvement.
insufficient information	No conclusion can yet be drawn about product impact.	There is no impact.
consistent evidence	The evidence supports expanding the pilot under monitoring.	The evidence guarantees success.

ACTIVITY 2: DESCRIBE, THEN INTERPRET**ACTIVIDAD 2: DESCRIBE Y LUEGO INTERPRETA**

Write one observation and one cautious interpretation for each fictional result: A) overdue actions 14% → 9%; B) deviation closure median 31 → 28 days; C) three temperature alarms in 40 shipments, all from one route.

Escribe una observación y una interpretación prudente para cada resultado ficticio.

CHAPTER 04 | B1

Grammar for study and project results

Gramática para resultados de estudios y proyectos

TENSE	USE	EXAMPLE	TIME SIGNAL
past simple	finished activity at a finished time	The pilot started in March and ended in May.	in May, last quarter
present perfect	result or experience connected to now	We have completed four reviews so far.	so far, already, yet
present perfect continuous	ongoing activity or duration	We have been monitoring the route for six weeks.	for, since, recently
past perfect	earlier event before another past event	The team had approved the plan before the issue occurred.	before, by the time

ACTIVE	PASSIVE	PRESENTATION EFFECT
The lab analysed 24 samples.	Twenty-four samples were analysed.	Passive keeps focus on samples/process.
QA confirmed the assessment.	The assessment was confirmed by QA.	Active makes responsibility prominent.
The team has closed five actions.	Five actions have been closed.	Choose based on whether actor or result matters.

ACTIVITY 3: TENSE AND FOCUS

ACTIVIDAD 3: TIEMPO Y ENFOQUE

Complete with the best tense. Then decide whether active or passive voice is more useful for the slide.

Completa con el tiempo correcto y decide si conviene voz activa o pasiva.

1 We ____ (complete) the pilot last Friday.

2 The team ____ (monitor) the signal since January.

3 QA ____ already ____ (approve) three actions.

4 By the time the meeting began, the site ____ (submit) the missing record.

5 Twenty-four samples ____ (analyse) during the study.

PRECISE. CAUTIOUS. ACTIONABLE.

35

CHAPTER 04 | MODEL

Model: evidence-to-decision update

Modelo: actualización de evidencia a decisión

FICTIONAL PRESENTATION SCRIPT / GUION FICTICIO

Good morning. Today I will summarise the six-week RouteSafe pilot and request a decision on the next phase. This is an operational training case; it does not assess product quality or clinical performance.

The pilot included 12 temperature-controlled shipments across two routes. First, all shipments arrived within the planned delivery window. Two alarms were recorded on Route B, while none were recorded on Route A. Both Route B alarms came from the same logger position near the outer wall of the container.

The key point is that the alarms show a location-specific pattern, but the sample is too small to establish a general cause. The placement assessment is still in progress. In addition, the team has not compared seasonal conditions.

I recommend extending the pilot for eight weeks with three controls: standardised logger placement, photographs at packing and a documented route-condition review. Success would mean complete placement records for every shipment and enough data to assess whether the pattern persists.

To conclude, the pilot identified a question that requires controlled follow-up. I am requesting approval for the extended pilot, not a conclusion about product impact.

APOYO EN ESPAÑOL

Buenos días. Hoy resumiré el piloto RouteSafe de seis semanas y solicitaré una decisión sobre la siguiente fase. Es un caso operativo de capacitación; no evalúa calidad del producto ni desempeño clínico.

El piloto incluyó 12 envíos con temperatura controlada en dos rutas. Todos llegaron dentro del plazo previsto. Se registraron dos alarmas en la Ruta B y ninguna en la A. Ambas alarmas de la Ruta B procedían de la misma posición del registrador cerca de la pared exterior.

El punto clave es que las alarmas muestran un patrón por ubicación, pero la muestra es demasiado pequeña para establecer una causa general. La evaluación de posición sigue en curso. Además, el equipo no ha comparado condiciones estacionales.

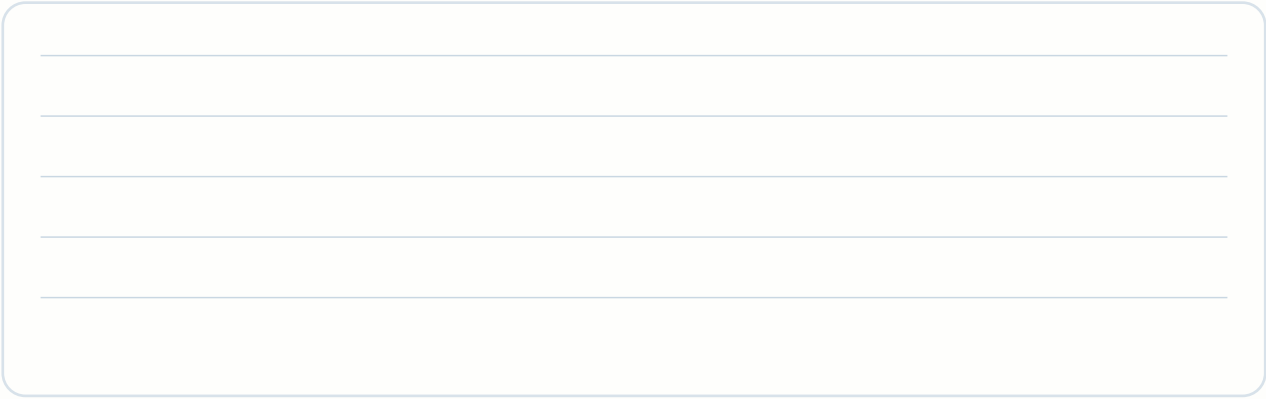
Recomiendo ampliar el piloto ocho semanas con tres controles: posición estandarizada, fotografías al empacar y revisión documentada de condiciones de ruta. El éxito sería contar con registros completos de posición y datos suficientes para evaluar si el patrón persiste.

En conclusión, el piloto identificó una pregunta que requiere seguimiento controlado. Solicito aprobación para ampliar el piloto, no una conclusión sobre impacto en producto.

ACTIVITY 4: FIND THE GUARDRAILS**ACTIVIDAD 4: ENCUENTRA LOS LÍMITES**

Identify the scope statement, three observations, two limitations, recommendation, success measure and exact decision requested.

Identifica alcance, tres observaciones, dos limitaciones, recomendación, medida de éxito y decisión solicitada.



A large rectangular box with a light blue border and rounded corners, containing five horizontal lines for writing.

CHAPTER 04 | B2

Q&A without guessing

Preguntas y respuestas sin adivinar

MOVE	USEFUL LANGUAGE	WHY IT HELPS
clarify	Are you asking about the alarm pattern or the product assessment?	prevents answering the wrong question
answer directly	Two alarms were recorded, both on Route B.	gives the verified fact first
state a limit	The pilot was not designed to determine product impact.	protects the scope
avoid speculation	We do not yet have evidence to answer that.	keeps uncertainty visible
commit	I will verify the calibration status and respond by 15:00 tomorrow.	creates a documented next action
bridge	The detailed answer is in the appendix; the decision today concerns the extended pilot.	returns to the decision

ACTIVITY 5: ANSWER OR DEFER

ACTIVIDAD 5: RESPONDE O POSPÓN

Draft a safe response to each question using only the model information. If the answer is unknown, state what you will verify and by when.

Redacta una respuesta segura usando solo la información del modelo. Si no se sabe, indica qué verificarás y cuándo.

1 Did the alarms affect product quality?

2 Why did Route B have alarms?

3 Is one route safer than the other?

4 What will the extended pilot change?

5 Who approved the logger position?

CHAPTER 04 | PRODUCE

Presentation planner

Planificador de presentación

YOUR BRIEF / TU ENCARGO

Prepare a 4-6 minute presentation about a fictional or anonymised quality, clinical-operations, regulatory or supply project. Request one defined decision. Do not include confidential, patient-identifiable or unapproved promotional information.

Prepara una presentación de 4-6 minutos sobre un proyecto ficticio o anónimo de calidad, operaciones clínicas, regulación o suministro. Solicita una decisión definida. No incluyas información confidencial, identificable de pacientes ni promocional no aprobada.

ELEMENT	PLANNING NOTES / NOTAS
Audience and decision / Público y decisión	
Scope and exclusions / Alcance y exclusiones	
Three verified observations / Tres observaciones	
Interpretation and confidence / Interpretación y confianza	
Limitations / Limitaciones	
Options or recommendation / Opciones o recomendación	
Risk controls / Controles de riesgo	
Success measure / Medida de éxito	
Likely difficult question / Pregunta difícil	

Opening, signposts and final ask / Apertura, señalización y solicitud final

PRESENTATION CHECK / CONTROL DE PRESENTACIÓN

- ☐ Acronyms are defined. ☐ Units and denominators are visible. ☐ Observation and interpretation are separate.
☐ Limits are not hidden. ☐ The ask is within scope. ☐ I know what I will say when the answer is unknown.
☐ Las siglas están definidas. ☐ Unidades y denominadores son visibles. ☐ Observación e interpretación están separadas.
☐ Los límites no se ocultan. ☐ La solicitud está dentro del alcance. ☐ Sé qué decir cuando no conozco la respuesta.



Passive voice: useful for processes. Suspicious when nobody owns the action.

CHAPTER 05

Grammar for Precision and Responsibility

Gramática para precisión y responsabilidad

Advanced grammar is useful when it clarifies sequence, responsibility, condition, uncertainty or evidence. It becomes risky when complexity hides the actor, weakens urgency or makes an unsupported claim sound authoritative.

APOYO EN ESPAÑOL

La gramática avanzada es útil cuando aclara secuencia, responsabilidad, condición, incertidumbre o evidencia. Se vuelve riesgosa cuando la complejidad oculta al actor, reduce la urgencia o hace que una afirmación no respaldada parezca autoritativa.

YOU WILL LEARN	APRENDERÁS
1. control time relationships in investigations and updates	controlar relaciones temporales en investigaciones y actualizaciones
2. choose active or passive voice according to purpose	elegir voz activa o pasiva según el propósito
3. use conditionals, relative clauses and reporting structures accurately	usar condicionales, relativas y estilo indirecto con precisión

CHAPTER 05 | B1-B2

Build the investigation timeline

Construye la cronología de investigación

FORM	TIME RELATIONSHIP	PHARMA EXAMPLE	ESPAÑOL
past simple	finished event	The alarm occurred at 09:12.	evento terminado
past continuous	activity in progress around a past event	The line was running when the alarm occurred.	actividad en curso
past perfect	earlier event before another past event	Maintenance had ended before the alarm occurred.	pasado anterior
present perfect	past result connected to now	The team has completed the initial assessment.	resultado relevante ahora
present perfect continuous	activity continuing to now	The team has been monitoring the process since Monday.	actividad que continúa
future perfect	expected completion by a future point	QA will have reviewed the evidence by Friday.	acción completada antes de un punto futuro

SEQUENCE IS EVIDENCE / LA SECUENCIA ES EVIDENCIA

Use the past perfect only when the earlier event needs to be explicit. 'Maintenance had ended before the alarm occurred' establishes sequence; it does not establish cause.

Usa el pasado perfecto cuando sea necesario hacer explícito el evento anterior. La secuencia no establece por sí sola una causa.

ACTIVITY 1: PUT TIME IN ORDER

ACTIVIDAD 1: ORDENA EL TIEMPO

Complete with the best tense. Then number the events in chronological order.

Completa con el tiempo adecuado y ordena cronológicamente los eventos.

- 1 By the time QA arrived, the operator _____ already _____ (stop) the line.
- 2 The team _____ (review) the alarm since Tuesday.
- 3 Maintenance _____ (finish) at 09:00.
- 4 The line _____ (run) normally when the alarm appeared.
- 5 We _____ (complete) three interviews so far.
- 6 The technical reviewer _____ (finish) the assessment by Friday.

CHAPTER 05 | B1-B2

Active, passive and accountable

Activa, pasiva y responsable

PURPOSE	BEST DEFAULT	EXAMPLE	WHY
name the responsible actor	active	QA will review the assessment by Friday.	owner is visible
focus on a controlled process	passive	Samples are stored at the defined temperature.	process matters more than routine actor
report an unknown actor	passive + state unknown	One entry was changed; the user has not yet been identified.	does not invent responsibility
describe immediate control	active	The operator stopped the line and secured the area.	action and actor are important
summarise a result	active or passive	QC confirmed the result. / The result was confirmed by QC.	choose the intended focus

PASSIVE FORMS / FORMAS PASIVAS

TIME	FORM	EXAMPLE
present routine	am/is/are + participle	The audit trail is reviewed weekly.
past event	was/were + participle	The record was approved on Monday.
current result	has/have been + participle	The three actions have been closed.
future action	will be + participle	The assessment will be documented tomorrow.
modal	modal + be + participle	The sample must be handled under the approved procedure.

ACTIVITY 2: FIND THE HIDDEN OWNER

ACTIVIDAD 2: ENCUENTRA AL RESPONSABLE OCULTO

Rewrite in active voice where ownership matters. Keep passive voice where it improves process focus.
Reescribe en activa cuando importe la responsabilidad. Mantén la pasiva cuando mejore el enfoque del proceso.

- 1 The investigation will be completed by Thursday. (Owner known: Site QA.)
- 2 Samples are stored in monitored units.
- 3 It was decided that training should be repeated. (Decision-maker known: Change Board.)
- 4 The alarm was acknowledged after 18 minutes. (User not yet identified.)
- 5 The impact assessment has been approved. (Approver relevant: Quality Director.)

CHAPTER 05 | B2

Conditionals and recommendations

Condicionales y recomendaciones

STRUCTURE	USE	EXAMPLE	RISK
zero: if + present, present	automatic or general process	If an alarm triggers, the system records an event.	Do not use for a one-time uncertain outcome.
first: if + present, will	real future possibility	If the review confirms the gap, QA will open a CAPA.	Do not put normal future 'will' after if.
second: if + past, would	hypothetical option	If we added a second reviewer, we would reduce dependency on one person.	Signals hypothesis, not plan.
third: if + past perfect, would have	alternative past	If the record had been checked, the error would have been found earlier.	Avoid using it to assign blame casually.
inversion: should + subject	formal possible condition	Should the timeline change, Regulatory will update the plan.	Formal; keep it clear.

RECOMMENDATION FORM	EXAMPLE	NOTE
recommend + -ing	We recommend extending the monitoring period.	common and direct
recommend that + subject + base verb	We recommend that the site repeat the training.	mandative form; 'repeats' also appears in some varieties
It is essential that + base verb	It is essential that each function provide an owner.	formal requirement language; use only with a basis
It may be worth + -ing	It may be worth reviewing similar records.	softened suggestion

ACTIVITY 3: COMPLETE THE CONDITIONS

ACTIVIDAD 3: COMPLETA LAS CONDICIONES

Use the correct conditional form. Then label each as process, likely future, hypothesis or alternative past.
Usa el condicional correcto y clasifica su función.

- 1 If a required field _____ (be) empty, the system blocks submission.
- 2 If QA _____ (approve) the plan today, training will begin Monday.
- 3 If we _____ (have) a shared glossary, mixed-audience meetings would be easier.
- 4 If the log _____ (review) earlier, the discrepancy would have been identified.
- 5 Should the authority _____ (request) clarification, Regulatory will coordinate the response.

CHAPTER 05 | B2

Relative clauses and reported decisions

Oraciones relativas y decisiones indirectas

FORM	FUNCTION	EXAMPLE	PUNCTUATION
that / which	identify a thing	The method that failed the check is under review.	No commas when information is essential.
who	identify a person	The reviewer who approved the record is available.	No commas when essential.
whose	show possession	We contacted the site whose record was incomplete.	Followed by a noun.
where	identify a place or situation	This is the step where the value is entered.	Do not add another place preposition.
non-defining which	add extra information	The pilot, which ended in May, included 12 shipments.	Use commas; do not use 'that.'

DIRECT MESSAGE	REPORTED MESSAGE	CHANGE
QA said, 'The review is open.'	QA said that the review was open.	present → past
The lead said, 'We have completed the assessment.'	The lead said that they had completed the assessment.	present perfect → past perfect
Regulatory said, 'We will reply tomorrow.'	Regulatory said that they would reply the next day.	will → would; time shifts
The chair asked, 'Can you own the action?'	The chair asked whether I could own the action.	question becomes statement order
QA said, 'Do not restart the line.'	QA instructed the team not to restart the line.	instruct + object + not to

ACTIVITY 4: REPORT WITHOUT DISTORTING**ACTIVIDAD 4: INFORMA SIN DISTORSIONAR**

Rewrite each message in reported speech. Keep the speaker, certainty and requested action accurate.
Reescribe cada mensaje en estilo indirecto, manteniendo hablante, certeza y acción solicitada.

- 1 'The sample may have been exposed,' the specialist said.
- 2 'We cannot confirm the root cause yet,' QA said.
- 3 'Please provide the source record by Friday,' the auditor asked.
- 4 'Did the site use the current form?' the monitor asked.
- 5 'I completed the review yesterday,' Ana said.

CHAPTER 05 | PRODUCE

Writing practice: quality recommendation

Práctica escrita: recomendación de calidad

FICTIONAL BRIEF / CASO FICTICIO

Three departments use separate spreadsheets to track training for one shared procedure. The procedure has changed twice in six months. In a sample of 30 records, four completion dates differed between trackers; the approved learning system contained the correct evidence. No missed training has been confirmed. A system improvement project is planned next quarter.

Tres departamentos usan hojas de cálculo separadas para seguir la capacitación de un procedimiento compartido. El procedimiento cambió dos veces en seis meses. En una muestra de 30 registros, cuatro fechas diferían entre hojas; el sistema aprobado contenía la evidencia correcta. No se ha confirmado capacitación omitida. Hay un proyecto de mejora previsto para el próximo trimestre.

TASK: WRITE A 220-280 WORD RECOMMENDATION

TAREA: ESCRIBE UNA RECOMENDACIÓN DE 220-280 PALABRAS

Separate observation, current impact, risk, short-term control and long-term recommendation. Use one past perfect, two passives, two active owner statements, one conditional, one relative clause and two cautious claims. Separa observación, impacto actual, riesgo, control a corto plazo y recomendación a largo plazo. Usa pasado perfecto, dos pasivas, dos responsables en activa, un condicional, una relativa y dos afirmaciones prudentes.

GRAMMAR AUDIT / AUDITORÍA GRAMATICAL

- ☐ Time sequence is unambiguous. ☐ Passive voice does not hide a known owner. ☐ Conditions match the degree of reality. ☐ Reported messages preserve certainty. ☐ Complex sentences remain easy to scan.
- ☐ La secuencia temporal es inequívoca. ☐ La pasiva no oculta responsables conocidos. ☐ Los condicionales coinciden con la realidad. ☐ El estilo indirecto conserva la certeza. ☐ Las oraciones complejas siguen siendo claras.



Negotiation status: protecting the molecule, the timeline, the budget and everyone's blood pressure.

CHAPTER 06

Real-World Cross-Functional Scenarios

Escenarios multifuncionales reales

Pharma professionals rarely solve a problem inside one function. These scenarios combine commercial constraints, technical evidence, quality responsibilities and regulatory commitments so that language supports a workable, documented agreement.

APOYO EN ESPAÑOL

Los profesionales farmacéuticos rara vez resuelven un problema dentro de una sola área. Estos escenarios combinan límites comerciales, evidencia técnica, responsabilidades de calidad y compromisos regulatorios para lograr acuerdos viables y documentados.

YOU WILL LEARN	APRENDERÁS
1. negotiate positions, interests, scope and trade-offs	negociar posturas, intereses, alcance y concesiones
2. write a precise clarification and commitment response	escribir una aclaración y respuesta de compromiso precisas
3. lead a cross-functional scenario from facts to action	liderar un escenario multifuncional desde hechos hasta acción

CHAPTER 06 | B2

Partnership and supplier negotiation

Negociación con socios y proveedores

A position is the stated request: 'We need exclusive rights.' An interest is the underlying need: 'We need confidence that our investment is protected.' Exploring interests creates options without weakening essential quality, safety or compliance requirements.

APOYO EN ESPAÑOL

Una postura es la solicitud declarada: 'Necesitamos derechos exclusivos'. Un interés es la necesidad subyacente: 'Necesitamos seguridad de que nuestra inversión está protegida'. Explorar intereses crea opciones sin debilitar requisitos esenciales de calidad, seguridad o cumplimiento.

TERM	PLAIN MEANING	NEGOTIATION QUESTION	ESPAÑOL
scope	work, products, markets or activities included	What exactly is in and out of scope?	alcance
milestone	defined event linked to timing or payment	What evidence confirms the milestone?	hito
deliverable	document, data or output to be provided	Who accepts the deliverable and by when?	entregable
intellectual property (IP)	rights in inventions, data or know-how	Which background and new IP are covered?	propiedad intelectual
data access	permission to view or use defined data	Who can access which data for what purpose?	acceso a datos
licence / license	permission to use defined rights	Is the licence exclusive, limited or time-bound?	licencia
liability	legal responsibility for defined loss or harm	Which team must review this clause?	responsabilidad legal
service level	measurable performance expectation	How will performance be measured and reported?	nivel de servicio
termination	conditions for ending the agreement	What obligations continue after termination?	terminación

MOVE	TACTFUL LANGUAGE
explore interest	Could you explain what risk the exclusivity request is intended to manage?
state a boundary	We cannot reduce the quality requirement, but we can discuss the review sequence.
offer conditionally	If you provide the validation package by 15 June, we could bring the audit forward.
trade	We may have flexibility on timing in exchange for earlier data access.
test agreement	Would that address the concern without changing the approved specification?
reserve review	This point remains subject to Quality and Legal review.

CHAPTER 06 | MODEL

Negotiation in action

Negociación en acción

FICTIONAL DIALOGUE / DIÁLOGO FICTICIO

Amira (sponsor): We need the method-transfer package by 30 June to protect the study timeline.

Tom (laboratory): We can provide the protocol and training records by then, but the final comparative report depends on the second run.

Amira: Which part of the package is creating the dependency?

Tom: The acceptance criterion requires two comparative runs. The second run is booked for 26 June, so review cannot be complete by the 30th.

Amira: We cannot change the approved criterion. Could you provide a controlled interim package on 30 June and the final report one week later?

Tom: That could work if the interim package is clearly marked as incomplete and cannot be used for a transfer decision.

Amira: Agreed. We will use it only for planning. If the second run meets the criterion, you will issue the final report by 7 July. If it does not, you will notify us within one working day and open the agreed investigation process.

Tom: Yes, subject to Quality approval of the interim-package wording.

Amira: To confirm: protocol and training records by 30 June, controlled interim package for planning only, final report targeted for 7 July, and immediate notification if the criterion is not met. Quality approval of the wording is the open condition.

APOYO EN ESPAÑOL

Amira (patrocinador): Necesitamos el paquete de transferencia del método antes del 30 de junio para proteger el cronograma del estudio.

Tom (laboratorio): Podemos entregar el protocolo y registros de capacitación para esa fecha, pero el informe comparativo final depende de la segunda corrida.

Amira: ¿Qué parte del paquete crea la dependencia?

Tom: El criterio de aceptación exige dos corridas comparativas. La segunda está programada para el 26, así que la revisión no puede terminar el 30.

Amira: No podemos cambiar el criterio aprobado. ¿Podrías entregar un paquete interino controlado el 30 y el informe final una semana después?

Tom: Podría funcionar si se marca claramente como incompleto y no se usa para decidir la transferencia.

Amira: De acuerdo. Solo lo usaremos para planificación. Si la segunda corrida cumple el criterio, emitirán el informe final antes del 7 de julio. Si no, nos avisarán en un día hábil y abrirán el proceso de investigación acordado.

Tom: Sí, sujeto a aprobación de Calidad del texto del paquete interino.

Amira: Confirmando: protocolo y registros el 30 de junio, paquete interino solo para planificación, informe final previsto para el 7 de julio y aviso inmediato si no se cumple el criterio. La aprobación de Calidad es la condición abierta.

ACTIVITY 1: MAP THE AGREEMENT**ACTIVIDAD 1: TRAZA EL ACUERDO**

Identify the original positions, underlying interests, non-negotiable criterion, proposed trade, two conditions, agreed deliverables, dates, scope restriction and open approval.

Identifica posturas, intereses, criterio no negociable, concesión, condiciones, entregables, fechas, límite de uso y aprobación abierta.

CHAPTER 06 | DOCUMENT

Regulatory clarification: answer the question asked

Aclaración regulatoria: responde la pregunta formulada

FICTIONAL AUTHORITY QUESTION / PREGUNTA FICTICIA
'Clarify whether all commercial-scale batches were manufactured with the same mixing time described in section 3.2.P.3.3. If not, identify the affected batches, provide the approved ranges and explain the assessment performed.'
'Aclare si todos los lotes a escala comercial se fabricaron con el mismo tiempo de mezclado descrito en la sección 3.2.P.3.3. En caso contrario, identifique los lotes afectados, proporcione los rangos aprobados y explique la evaluación realizada.'

RESPONSE MOVE	QUESTION TO CHECK	USEFUL OPENING
direct answer	What is the yes/no answer?	No. Two validation batches used a different time within the approved range.
scope	Which batches and period are covered?	The response covers batches V01-V03 manufactured in 2025.
evidence	Where is the controlled source?	The approved records are listed in Table 1.
explanation	Why did the difference occur?	The difference reflects the approved scale-dependent range.
assessment	What was evaluated, by whom and with what result?	The technical assessment evaluated mixing uniformity against the approved criteria.
commitment	Is future work promised? Who owns it and by when?	Regulatory will submit the updated table by 14 October.
quality check	Does the response claim more than the evidence?	Use exact batch IDs, ranges and approved conclusions.

ACTIVITY 2: BUILD THE RESPONSE PLAN

ACTIVIDAD 2: CREA EL PLAN DE RESPUESTA

Do not invent technical facts. List the precise information that Regulatory must obtain from Manufacturing, QA and the dossier owner before drafting the response.
No inventes hechos técnicos. Enumera la información precisa que Regulatory debe obtener de Manufactura, QA y el responsable del expediente.

FUNCTION	INFORMATION / EVIDENCE NEEDED	OWNER	DUE
Manufacturing			
QA			
Dossier owner			
Regulatory			

Draft clarification questions / Preguntas de aclaración

CHAPTER 06 | PRACTISE

Inspection-readiness scenario

Escenario de preparación para inspección

FICTIONAL FINDING / HALLAZGO FICTICIO

A readiness review finds that six meeting decisions are recorded in slide decks but not linked to the controlled project decision log. The decisions are consistent with the current plan. Owners are known for four; two need confirmation. No inspection request has been received.

Una revisión de preparación detecta seis decisiones registradas en presentaciones, pero no vinculadas al registro controlado de decisiones. Coinciden con el plan actual. Se conocen responsables de cuatro; faltan dos. No se ha recibido ninguna solicitud de inspección.

ACTIVITY 3: RUN THE READINESS HUDDLE

ACTIVIDAD 3: REALIZA LA REUNIÓN DE PREPARACIÓN

Roles: project lead, QA, document owner and functional representative. Clarify the gap, avoid claiming that records are inspection-ready, define immediate evidence controls, assign owners and agree the message to senior stakeholders.

Roles: líder del proyecto, QA, responsable documental y representante funcional. Aclara la brecha, evita afirmar que los registros están listos, define controles, responsables y mensaje a líderes.

Facts, current assessment, actions, escalation and exact stakeholder message

ACTIVIDAD 4: ESCRIBE LA ACTUALIZACIÓN EJECUTIVA

Escribe 150-190 palabras. Indica hallazgo, qué no está afectado, incógnitas, plan de corrección, responsables/plazos y cuándo se reevaluará la preparación.

CHAPTER 06 | PRODUCE

Capstone simulation: launch dependency

Simulación integradora: dependencia de lanzamiento

FICTIONAL CROSS-FUNCTIONAL CASE / CASO MULTIFUNCIONAL FICTICIO

A planned regional launch depends on packaging-line validation, final artwork approval and release of training materials. Validation execution finished on 2 November; the report is under review. Artwork contains one formatting discrepancy that does not change the approved wording, but the assessment is not complete. Training materials cannot be approved until both source documents are final. The launch date is 25 November. No function can independently approve launch readiness.

Un lanzamiento regional depende de validación de línea de envasado, aprobación final del material gráfico y liberación de materiales de capacitación. La ejecución terminó el 2 de noviembre; el informe está en revisión. El material gráfico contiene una discrepancia de formato que no cambia el texto aprobado, pero la evaluación no está completa. La capacitación no puede aprobarse hasta finalizar ambos documentos. El lanzamiento es el 25 de noviembre. Ninguna área puede aprobar la preparación por sí sola.

TASK A: PREPARE THE DECISION MEETING

TAREA A: PREPARA LA REUNIÓN DE DECISIÓN

Assign Regulatory, QA, Validation, Supply and Commercial roles. Prepare facts, dependencies, decision criteria, options, risk language and the exact decisions that can and cannot be taken today.

Asigna roles de Regulatory, QA, Validación, Suministro y Comercial. Prepara hechos, dependencias, criterios, opciones, lenguaje de riesgo y decisiones posibles e imposibles hoy.

ROLE	PRIORITY	EVIDENCE	QUESTION	BOUNDARY
Regulatory				
QA				
Validation				
Supply				
Commercial				

Meeting opening and decision criteria / Apertura y criterios

TASK B: DOCUMENT THE OUTCOME

TAREA B: DOCUMENTA EL RESULTADO

After the simulation, write the decision, conditions, unresolved points, actions, owners, dates and escalation path. If the group cannot decide, state exactly what evidence is required and when it will reconvene.

Después de la simulación, escribe decisión, condiciones, puntos pendientes, acciones, responsables, fechas y ruta de escalado. Si no pueden decidir, indica la evidencia necesaria y cuándo se reunirán de nuevo.



Fluency upgrade installed. Side effect: volunteering to present.

CHAPTER 07

Confidence Through Deliberate Practice

Confianza mediante práctica deliberada

Confidence in pharma English is not the absence of uncertainty. It is the ability to prepare, define terms, ask for clarification, state limits and follow through on promised actions. Deliberate practice turns those behaviours into habits.

APOYO EN ESPAÑOL

La confianza en inglés farmacéutico no es la ausencia de incertidumbre. Es la capacidad de prepararse, definir términos, pedir aclaración, indicar límites y cumplir acciones prometidas. La práctica deliberada convierte estos comportamientos en hábitos.

YOU WILL LEARN	APRENDERÁS
1. build a repeatable vocabulary and pronunciation system	crear un sistema repetible de vocabulario y pronunciación
2. request, give and use feedback constructively	pedir, ofrecer y usar comentarios de forma constructiva
3. complete a final cross-functional communication package	completar un paquete final de comunicación multifuncional

CHAPTER 07 | BUILD THE HABIT

A deliberate practice loop

Ciclo de práctica deliberada

STEP	ACTION	PHARMA EXAMPLE	EVIDENCE OF PROGRESS
1 Notice	capture language from approved, non-confidential materials	'impact remains under assessment'	source and context recorded
2 Define	write a plain-English meaning and Spanish support	not the same as 'no impact'	definition is accurate
3 Produce	use the phrase in a new sentence or spoken update	Impact remains under assessment pending reconciliation.	sentence fits the context
4 Record	record a 30-60 second explanation	explain fact, uncertainty and action	clear pace and stress
5 Feedback	ask one specific question	Was my distinction between fact and assessment clear?	one actionable comment
6 Reuse	use the improved phrase in a later task	meeting, email and slide	accurate use in three contexts

PRONUNCIATION FOR CLARITY / PRONUNCIACIÓN PARA CLARIDAD

HABIT	EXAMPLE	PRACTICE
stress the key word	The impact is NOT yet determined.	Underline the contrast word before speaking.
chunk long noun phrases	final / comparative method-transfer report	Mark short meaning groups with slashes.
say letters and numbers separately	Q-204; 2-8°C; 15:00 UTC	Confirm identifiers, units and timezone.
define before shortening	corrective and preventive action - CAPA	Practise the full form and acronym together.
pause before the action	The evidence is incomplete. / Therefore, we will review...	Use silence to separate evidence from action.

ACTIVITY 1: BUILD A LANGUAGE CARD

ACTIVIDAD 1: CREA UNA TARJETA DE LENGUAJE

Choose one phrase from this workbook. Record meaning, context, unsafe alternative, pronunciation chunking and your own example.
Elige una frase del cuaderno. Registra significado, contexto, alternativa insegura, segmentación de pronunciación y ejemplo propio.

PHRASE	PLAIN MEANING	CONTEXT	AVOID	MY EXAMPLE

Pronunciation chunks and notes / Segmentos y notas

CHAPTER 07 | COLLABORATE

Feedback that improves the message

Comentarios que mejoran el mensaje

PURPOSE	USEFUL LANGUAGE	ESPAÑOL
request focused feedback	Could you tell me whether the action and deadline were clear?	¿Podrías decirme si la acción y el plazo quedaron claros?
check interpretation	What conclusion did you take from the data slide?	¿Qué conclusión obtuviste de la diapositiva?
give specific feedback	The observation was clear, but the current assessment sounded final.	La observación fue clara, pero la evaluación sonó definitiva.
ask for an example	Which sentence sounded ambiguous?	¿Qué oración sonó ambigua?
confirm improvement	I will change 'no impact' to 'impact has not yet been identified.'	Cambiaré 'sin impacto' por 'aún no se ha identificado impacto'.
close the loop	I revised the summary. Could you check the owner-deadline pairs again?	Revisé el resumen. ¿Puedes comprobar de nuevo responsables y plazos?

CULTURAL RANGE WITHOUT STEREOTYPES / VARIEDAD CULTURAL SIN ESTEREOTIPOS

Individuals and teams differ in directness, turn-taking, hierarchy and comfort with silence. Do not guess from nationality. Make the working norm explicit: how concerns are raised, how disagreement is recorded, who decides, when silence means reflection rather than agreement, and how urgent issues are escalated.

APOYO EN ESPAÑOL
Las personas y equipos difieren en franqueza, turnos de palabra, jerarquía y comodidad con el silencio. No supongas según nacionalidad. Explicita la norma de trabajo: cómo se plantean inquietudes, se registra el desacuerdo, quién decide, cuándo el silencio significa reflexión y cómo se escalan asuntos urgentes.

SITUATION	CLEAR TEAM NORM
raising concern	Anyone may pause the discussion and state the evidence or missing evidence.
disagreement	The minutes record the decision, rationale and unresolved dissent where relevant.
decision	The chair states who has decision authority before discussion begins.
silence	The chair checks explicitly; silence is not treated as approval.
urgent escalation	The team follows the agreed process and names the responsible contact.

ACTIVITY 2: TURN FEEDBACK INTO A REVISION

ACTIVIDAD 2: CONVIERTE COMENTARIOS EN REVISIÓN

Original: 'The issue is minor, and everything should be fine. The investigation will be completed soon.' Feedback: risk basis unclear; owner and date missing; 'fine' overstates certainty. Rewrite the update.

Original: 'El problema es menor y todo debería estar bien. La investigación terminará pronto'. Comentarios: base de riesgo poco clara; faltan responsable y fecha; 'bien' exagera certeza. Reescribe.

CHAPTER 07 | PLAN

Thirty-day confidence plan

Plan de confianza de treinta días

SMALL, SPECIFIC, REPEATED / PEQUEÑO, ESPECÍFICO, REPETIDO

Choose one communication behaviour, not a vague goal such as 'be fluent.' Practise it in short cycles and collect evidence that another person understood the intended meaning.

Elige un comportamiento comunicativo, no una meta vaga como 'hablar con fluidez'. Practícalo en ciclos cortos y reúne evidencia de que otra persona entendió el significado previsto.

WEEK	FOCUS	THREE PRACTICES	FEEDBACK SOURCE	EVIDENCE
1	Define acronyms and role language			
2	State facts, uncertainty and action			
3	Lead a concise meeting update			
4	Present evidence and answer questions			

PERSONAL LANGUAGE BANK / BANCO PERSONAL

PHRASE	FUNCTION	MY EXAMPLE	REVIEW DATE

The one behaviour I will measure / El comportamiento que mediré

CHAPTER 07 | CAPSTONE

Final communication package

Paquete final de comunicación

FICTIONAL CASE: GLOBAL PROCEDURE ROLLOUT / CASO: IMPLEMENTACIÓN GLOBAL

A revised global complaint-handling procedure is planned to become effective on 1 February. The approved English source is final. Spanish and Portuguese translations are under linguistic review. Three sites completed role mapping; two have not. The learning system is configured but cannot assign training until each site confirms roles. A pilot at one site identified two confusing screenshots, which have been corrected in the draft training guide. The procedure effective date has not changed. The global team needs a readiness decision on 15 January.

Un procedimiento global revisado de gestión de quejas entrará en vigor el 1 de febrero. La fuente inglesa aprobada es final. Las traducciones al español y portugués están en revisión lingüística. Tres centros completaron el mapeo de puestos; dos no. El sistema está configurado, pero no puede asignar capacitación hasta confirmar los puestos. Un piloto detectó dos capturas confusas, corregidas en el borrador de la guía. La fecha no ha cambiado. El equipo global necesita una decisión de preparación el 15 de enero.

FACT / HECHO	UNKNOWN / DESCONOCIDO	DEPENDENCY / DEPENDENCIA	DECISION NEEDED
English source final	translation completion dates	translations before local training	readiness path
3/5 sites mapped roles	owners/dates for 2 sites	role map before assignment	site conditions
system configured	assignment test result	roles loaded first	test timing
screenshots corrected in draft	approval date of guide	approved guide before training	document owner

TASK A: PREPARE THE READINESS MEETING

TAREA A: PREPARA LA REUNIÓN DE PREPARACIÓN

Define audience, chair, decision authority, decision criteria, required evidence, likely disagreement, escalation route and the exact decision that can be taken on 15 January.

Define público, facilitador, autoridad de decisión, criterios, evidencia requerida, desacuerdo probable, escalado y decisión exacta del 15 de enero.

CHAPTER 07 | WRITE

Capstone document 1: readiness update

Documento 1: actualización de preparación

WRITE 220-280 WORDS
ESCRIBE 220-280 PALABRAS

Write a cross-functional readiness update. Use sections for status, verified facts, open evidence, dependencies, actions and decision required. Include at least five owner-date pairs and do not change the stated effective date.
Escribe una actualización multifuncional. Usa secciones para estado, hechos, evidencia pendiente, dependencias, acciones y decisión requerida. Incluye al menos cinco pares responsable-fecha y no cambies la fecha de vigencia.

CHAPTER 07 | PRESENT & FOLLOW UP

Capstone documents 2-3

Documentos integradores 2-3

DOCUMENT 2: FOUR-MINUTE READINESS PITCH**DOCUMENTO 2: PRESENTACIÓN DE CUATRO MINUTOS**

Plan the opening, scope, three facts, two dependencies, current risk, decision criteria, recommendation and exact ask. Prepare one response to an unknown question.

Planifica apertura, alcance, tres hechos, dos dependencias, riesgo actual, criterios, recomendación y solicitud exacta. Prepara una respuesta ante una pregunta desconocida.

DOCUMENT 3: DECISION FOLLOW-UP EMAIL

DOCUMENTO 3: CORREO DE SEGUIMIENTO

After a simulated decision, write 150-190 words confirming the decision, rationale, conditions, actions, owners, dates, unresolved points and next review. If no decision is reached, state the missing evidence precisely.

Después de una decisión simulada, escribe 150-190 palabras con decisión, justificación, condiciones, acciones, responsables, fechas, puntos pendientes y próxima revisión. Si no hay decisión, indica la evidencia faltante.

CHAPTER 07 | ASSESS

Final rubric and reflection

Rúbrica final y reflexión

CRITERION	4 - CONTROLLED	3 - SECURE	2 - DEVELOPING	1 - RISKY
Facts & evidence	facts, inference and limits are consistently separate	mostly accurate separation	some blurred claims	unsupported or misleading claims
Purpose & scope	decision and exclusions are explicit	purpose is clear	scope is incomplete	purpose or scope is unclear
Actionability	every action has owner, date and status	most actions are actionable	several details missing	reader cannot act
Grammar & cohesion	controlled B2 range supports meaning	mostly accurate B1-B2	errors sometimes distract	errors obscure meaning
Tone & challenge	cautious, direct and respectful	professional tone	too vague or too blunt at times	tone hides urgency or creates friction
Audience & access	acronyms, units and detail are adapted	mostly audience-aware	some unexplained shorthand	message excludes or confuses audience
Follow-through	commitments and feedback loop are complete	next review is clear	partial follow-up	no closure path

FINAL SELF-ASSESSMENT / AUTOEVALUACIÓN FINAL

I CAN...	BEFORE	NOW	EVIDENCE
separate fact, assessment and action	1 2 3 4	1 2 3 4	
raise a concern and request evidence	1 2 3 4	1 2 3 4	
document an owner and due date	1 2 3 4	1 2 3 4	
present data without overclaiming	1 2 3 4	1 2 3 4	
answer honestly when evidence is missing	1 2 3 4	1 2 3 4	

The communication behaviour I will keep practising / El comportamiento que seguiré practicando

SELF-CHECK AND FACILITATOR GUIDE

Suggested Answer Key

Respuestas sugeridas

Closed tasks have suggested answers below. Open tasks should be evaluated for factual discipline, scope, actionability, language accuracy and professional tone. Technical decisions remain outside the workbook.

APOYO EN ESPAÑOL

Las actividades cerradas tienen respuestas sugeridas. Evalúa las tareas abiertas por disciplina factual, alcance, capacidad de acción, precisión lingüística y tono profesional. Las decisiones técnicas quedan fuera del cuaderno.

CHAPTER 1

Activity 1 possible leads: 1 R&D/QC; 2 Regulatory; 3 Manufacturing/QA; 4 Clinical Operations; 5 QC; 6 QA with the relevant function; 7 Supply Chain. Cross-functional contributions are expected.

Activity 2: 1 open a deviation; 2 meet specification; 3 identify a root cause; 4 implement CAPA; 5 review an audit trail; 6 release a batch; 7 raise a change control; 8 close an investigation.

Activity 3 sample: Observation - One logger recorded 10°C for 42 minutes; the labelled range is 2-8°C. Interpretation - This is a confirmed excursion, but product impact has not yet been assessed. Action - Keep the shipment in controlled hold and obtain logger placement, calibration and route evidence through the approved process.

Activity 4: 1 tests; 2 are reviewing; 3 has already completed; 4 am working; 5 maintains.

CHAPTER 2

Activity 1: 1 change-control meeting - impact assessment and approval path; 2 quality review - trend/assessment/actions; 3 S&OP or supply review - mitigation and forecast; 4 clinical team meeting - corrective coordination and escalation; 5 inspection-readiness meeting - gap and remediation plan.

Activity 2 samples: 1 Product impact has not yet been determined. 2 This alarm requires immediate review under the local process; please contact the named owner now. 3 What documented deadline and approval basis apply? 4 The small engineering run suggests a possible benefit, but it does not establish that the method is always better.

Activity 3: Objective = controls/investigation for Q-118. Observation = unlabelled tray found; no use identified. Unknowns = entry time and full reconciliation. Controls = stop, hold and secure. No restart decision. Actions = Sam/reconciliation/16:00; Ravi/identity/noon; Marta/assessment/tomorrow. Open risk = product impact.

ANSWER KEY

Suggested answers - Chapters 3-4

Respuestas sugeridas - Capítulos 3-4

CHAPTER 3

Activity 1: 1 contrast; 2 condition; 3 sequence; 4 result; 5 example.

Activity 2 possible corrections: 1 Maintenance ended before the alarm occurred; the cause is not yet known. 2 Although the sample met specification, the investigation remained open. 3 The audit trail was reviewed; however, two entries were not explained. 4 The first run was faster, but one run does not establish that the method is always superior. 5 Despite the incomplete form / Although the form was incomplete, it was approved.

Activity 3: Sequence = First; contrasts = however / Nevertheless; addition = In addition; result = Therefore; limitation = no root cause approved and disposition outside scope. Owner-date pairs: QA/assessment/10 September; Manufacturing/interview and review/9 September. The scope statement prevents the update from being mistaken for a disposition decision.

Activity 4: Answers vary. Strong versions state chronology with after/when, avoid because where cause is unknown, and use may indicate or is associated with where other explanations remain.

CHAPTER 4

Activity 1 sample technical: 'Three of 24 records required manual correction; each correction was traceable and reviewed, so the team is examining the error type and process step.' Executive: 'The pilot found a 12.5% manual-correction rate, with complete traceability. We need to decide whether to extend the pilot while addressing the correction pattern.'

Activity 2 samples: A Overdue actions fell by five percentage points, from 14% to 9%; this may indicate improvement, although no cause is established. B Median closure time fell by three days; the operational significance requires context. C Three alarms occurred among 40 shipments, all on one route; the clustering suggests a route-specific question for further assessment.

Activity 3: 1 completed; 2 has been monitoring; 3 has already approved; 4 had submitted; 5 were analysed. Voice choice depends on whether actor or process is the intended focus.

Activity 4: Scope = operational case, not product quality/clinical performance. Observations = 12 shipments, timing met, two Route B alarms / none Route A, same logger position. Limits = small sample and no seasonal comparison. Recommendation = eight-week controlled extension. Success = complete placement records and enough data to assess persistence. Ask = approval for extension only.

ANSWER KEY

Suggested answers - Chapters 5-7

Respuestas sugeridas - Capítulos 5-7

CHAPTER 5

Activity 1: 1 had already stopped; 2 has been reviewing; 3 finished; 4 was running; 5 have completed; 6 will have finished. Chronology: maintenance finished; line was running; alarm occurred; operator stopped line; current review/interviews; future completion.

Activity 2 possible: 1 Site QA will complete the investigation by Thursday. 2 Keep passive for the routine process. 3 The Change Board decided that the team should repeat training. 4 Keep passive and state that the user is not yet identified. 5 The Quality Director has approved the impact assessment.

Activity 3: 1 is - process; 2 approves - likely future; 3 had - hypothesis; 4 had been reviewed - alternative past; 5 request - formal possible condition.

Activity 4: 1 The specialist said that the sample might have been exposed. 2 QA said that they could not confirm the root cause yet. 3 The auditor asked us to provide the source record by Friday. 4 The monitor asked whether the site had used the current form. 5 Ana said that she had completed the review the previous day.

CHAPTER 6

Activity 1: Original positions = sponsor wants complete package by 30 June; laboratory cannot complete final report by then. Interests = protect timeline vs. preserve approved evidence requirements. Non-negotiable = two-run criterion. Trade = controlled interim package for planning plus later final report. Conditions = no transfer decision from interim package; Quality approval of wording. Dates = 30 June and 7 July. Notification = within one working day if criterion is not met.

Activity 2: Manufacturing should provide actual batch IDs, mixing times, approved ranges and source records; QA should provide approval status and assessment; dossier owner should verify the registered description and section; Regulatory should map each question to evidence, identify gaps and coordinate the controlled response. No values should be invented.

Activities 3-4 and capstone: Strong answers identify the documentation gap without claiming inspection readiness, state what remains unknown, preserve decision authority and attach owner-date pairs to every remediation action.

CHAPTER 7

Activity 2 sample: 'The initial assessment classifies the issue according to the approved process, but the final risk assessment remains open. Site QA owns the investigation and will provide the evidence review by 17:00 Thursday. Until then, the affected records remain under controlled review.' Other precise versions are possible.

Capstone: A strong package does not move the 1 February effective date, does not treat draft training material as approved, identifies the two unmapped sites, keeps translation and role mapping as dependencies, names decision criteria for 15 January and records what happens if evidence is incomplete.

OPEN TASKS / TAREAS ABIERTAS

Reward messages that are easy to verify and act on. Advanced vocabulary does not compensate for an unsupported claim, hidden owner or missing deadline.

Valora mensajes fáciles de verificar y ejecutar. El vocabulario avanzado no compensa una afirmación no respaldada, un responsable oculto o un plazo ausente.

REFERENCE | REFERENCIA

Reusable pharma communication bank

Banco reutilizable de comunicación farmacéutica

PURPOSE	ENGLISH	ESPAÑOL
state fact	The record shows...	El registro muestra...
separate inference	This may indicate..., but it does not establish...	Esto puede indicar..., pero no establece...
state unknown	We cannot yet determine...	Aún no podemos determinar...
challenge evidence	What evidence supports that conclusion?	¿Qué evidencia respalda esa conclusión?
protect scope	That decision is outside the scope of this review.	Esa decisión queda fuera del alcance de esta revisión.
assign action	X will complete Y by [date/time].	X completará Y antes de [fecha/hora].
record condition	Approval is subject to...	La aprobación está sujeta a...
avoid guessing	I will verify that point and respond by...	Verificaré ese punto y responderé antes de...
recommend	Based on the current evidence, we recommend...	Según la evidencia actual, recomendamos...
escalate	This meets the agreed escalation criterion.	Esto cumple el criterio de escalado acordado.
summarise	The decision, rationale and open conditions are...	La decisión, justificación y condiciones abiertas son...

TERMINOLOGY NOTE / NOTA TERMINOLÓGICA

USE CURRENT CONTROLLED SOURCES

Core distinctions were cross-checked against official ICH, EMA and FDA materials available in 2026. Definitions, reporting rules and responsibilities vary by jurisdiction, product and organisation. Always use current controlled requirements and local procedures.

Las distinciones principales se contrastaron con materiales oficiales de ICH, EMA y FDA disponibles en 2026. Las definiciones, reglas y responsabilidades varían según jurisdicción, producto y organización. Usa siempre requisitos vigentes y procedimientos locales controlados.

Official references: ICH E6(R3) Good Clinical Practice | EMA adverse-event glossary | EMA regulatory glossary | FDA CGMP overview

MY CONTROLLED LANGUAGE BANK / MI BANCO CONTROLADO

TERM / PHRASE	APPROVED MEANING	SOURCE / VERSION	MY EXAMPLE

YOU FINISHED / TERMINASTE

In regulated communication, confidence sounds like this: the facts are clear, the limits are visible and the next action has an owner.

En comunicación regulada, la confianza suena así: los hechos están claros, los límites son visibles y la próxima acción tiene responsable.