EFSP Auxiliary ESL Curriculum

Pharmaceutical Dialogue Lab

Realistic pharmaceutical-workplace dialogues, role-play cards, and debrief prompts for advanced ESL learners

Audience: instructors, pharmaceutical English coaches, clinical teams, regulatory teams, medical affairs teams, quality teams, market access teams, and peer practice cohorts

Focus: high-level professional English for pharmaceutical workplaces, including drug development, target product profile, IND, NDA, BLA, clinical trial design, GCP, endpoints, estimands, safety, pharmacovigilance, CMC, CGMP, quality events, regulatory strategy, labeling, medical affairs, promotion review, market access, RWE, lifecycle management, and realistic cross-functional dialogue.

Designed for advanced ESL learners who work in clinical development, clinical operations, regulatory affairs, pharmacovigilance, medical affairs, quality, CMC, manufacturing, biostatistics, data management, market access, commercial compliance, or pharma-adjacent roles.

Teaching stance: pharmaceutical English is evidence, safety, compliance, and cross-functional judgment under pressure. Learners need to be scientifically precise, operationally clear, patient-centered, and careful with claims. This curriculum teaches professional communication and judgment, not medical, regulatory, or legal advice.

How to Run the Dialogue Lab

1. Use groups of three: pharma professional, cross-functional stakeholder, observer.
2. Read the model dialogue once. Then replay it with a different therapeutic area, evidence package, timeline pressure, regulatory region, safety pattern, or launch constraint.
3. The observer listens for evidence discipline, patient-safety language, quality or compliance boundaries, document control, uncertainty clarity, and decision-ready next steps.
4. After each role-play, replay the hardest 30 seconds with a more precise pharma sentence.

Facilitator guardrail

Do not let learners hide behind acronyms. Ask them to define the evidence, controlling document, patient or product-quality risk, compliance boundary, owner, and decision needed.

1. TPP Debate: Scientifically Interesting vs Clinically Meaningful

Setting

A discovery team wants to advance a compound, but the development team is uncertain about the patient and evidence logic.

Speaker	Line
Discovery lead	The biomarker response is strong. We should move quickly.
Clinical development	The biology is promising, but the clinical target is not clear yet.
ESL learner	Before we commit to the next study, we need a sharper TPP: target population, expected clinical benefit, dose rationale, safety assumptions, comparator, endpoint, and differentiation from standard of care.
Discovery lead	The mechanism is novel.
ESL learner	Novel mechanism helps, but it does not replace evidence that patients, regulators, physicians, and payers will consider meaningful.

Language notes

- Scientific excitement should be connected to patient and development logic.
- TPP language keeps the team from confusing mechanism with product value.

Role-play variation

Observer checklist

- Did the learner separate data, interpretation, claim, and decision?
- Did the learner name patient safety, data integrity, product quality, or compliance risk?
- Did the learner use the relevant document boundary: protocol, label, SOP, quality record, or regulatory feedback?
- Did the learner give a concrete next step without overpromising?

2. IND Readiness: CMC Is Not Just a Detail

Setting

A team wants to file an IND quickly, but CMC documentation is incomplete.

Speaker	Line
Program lead	Clinical is ready. Let's file the IND next month.
CMC lead	The stability package and analytical validation are not complete.
ESL learner	An IND is not only a protocol. We need enough nonclinical, clinical, and CMC information to support safe human dosing and product quality. If CMC is incomplete, the clinical timeline may not be credible.
Program lead	Can we explain that the data are coming?
ESL learner	We can propose a plan, but we should not present future work as current readiness. Let's identify the minimum data needed and the regulatory risk of filing early.

Language notes

- Regulatory readiness must include quality and manufacturing evidence.
- Use 'minimum data needed' and 'regulatory risk' instead of blame.

Role-play variation

Observer checklist

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3. Endpoint Debate: Convenient vs Clinically Relevant

Setting

The team is choosing a primary endpoint for a Phase 2 trial.

Speaker	Line
Clinical operations	The biomarker endpoint is easier to measure and faster.
Medical lead	But it may not persuade physicians.
ESL learner	We should separate operational convenience from clinical relevance. If the biomarker is the primary endpoint, we need a strong rationale that it predicts patient benefit or supports the development decision.
Statistician	The study is not powered for the clinical endpoint.
ESL learner	Then we should be explicit: the study may be decision-enabling for dose and signal, but not definitive for clinical benefit.

Language notes

- Endpoint language should name what the study can and cannot prove.
- Operationally convenient endpoints may still need clinical justification.

Role-play variation

Observer checklist

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4. Enrollment Rescue: Protocol Burden and Site Reality

Setting

Enrollment is behind plan and the team is considering more sites.

Speaker	Line
Clinical operations	We are 40 percent behind enrollment. We should activate more sites.
Site manager	The current sites say the visit schedule is too burdensome.
ESL learner	More sites may help, but only if the protocol is feasible. We should examine screen failure reasons, visit burden, competing trials, eligibility criteria, and patient travel before adding cost.
Program lead	We need speed.
ESL learner	Agreed, but speed without feasibility will only create more underperforming sites. Let's propose a rescue plan with root cause, amendment options, and site-support actions.

Language notes

- Enrollment rescue should start with root cause, not only site count.
- Protocol burden language helps connect operations to data quality.

Role-play variation

Observer checklist

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5. Safety Signal: Possible Liver Risk

Setting

Several liver enzyme elevations have appeared across studies.

Speaker	Line
Safety physician	We have a cluster of ALT elevations.
Clinical lead	Are they related to the drug?
ESL learner	We should not jump to causality, but we also should not minimize it. Let's review timing, dose relationship, dechallenge, rechallenge, baseline risk factors, concomitant medications, seriousness, and whether the pattern changes the risk-benefit assessment.
Regulatory affairs	Do we need to notify FDA?
ESL learner	Let's assess seriousness, expectedness, reasonable possibility, and reporting timelines against the protocol, regulations, and safety SOPs.

Language notes

- Safety language should be calm, structured, and urgent where needed.
- Avoid both premature causality and premature reassurance.

Role-play variation

Observer checklist

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6. Data Readout: Statistically Significant but Modest Effect

Setting

A Phase 3 trial met the primary endpoint, but the effect size is small and safety events increased.

Speaker	Line
Executive	The p-value is positive. Can we call this a major breakthrough?
Biostatistician	The effect is statistically significant, but the confidence interval is narrow around a modest benefit.
ESL learner	We can say the primary endpoint was met, but we should not overstate clinical impact. The communication needs effect size, clinical relevance, safety profile, population, and comparison to current options.
Commercial	But we need a strong launch message.
ESL learner	A strong message must still be supportable. Overclaiming now may create regulatory, credibility, and MLR risk later.

Language notes

- Positive data still need clinical and safety context.
- Commercial excitement must stay inside evidence boundaries.

Role-play variation

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7. Quality Deviation: Batch Release Pressure

Setting

A batch is needed for launch supply, but an OOS result is under investigation.

Speaker	Line
Supply lead	If we do not release this batch, launch inventory is at risk.
Quality	The OOS investigation is not closed.
ESL learner	Supply pressure does not remove the need for quality disposition. We need documented root cause, impact assessment, and QA approval before release. If the batch cannot be released, we should communicate supply risk and mitigation options.
Supply lead	Can we release with a memo?
ESL learner	Only if the quality system supports that conclusion. The decision must be evidence-based, documented, and approved through the proper process.

Language notes

- Quality decisions must not be framed as paperwork obstacles.
- Use documentation and process language rather than personal disagreement.

Role-play variation

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8. Promotional Claim Review: Subgroup Data

Setting

Marketing wants to use a subgroup result in launch materials.

Speaker	Line
Marketing	The subgroup response looks impressive. Can we make it the headline?
Medical reviewer	It was exploratory and not powered.
ESL learner	The subgroup may be scientifically interesting, but as a promotional headline it could be misleading. We need to check whether the claim is consistent with approved labeling, adequately supported, and presented with appropriate context and risk information.
Marketing	Can we say 'especially effective' in that subgroup?
ESL learner	Not unless that claim is supported and approved. We can discuss a balanced, label-consistent statement or keep the subgroup in scientific exchange if appropriate.

Language notes

- MLR language should distinguish evidence interest from promotional support.
- A true statement can still be misleading without context.

Role-play variation

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9. MSL Boundary: Unsolicited Off-Label Question

Setting

A physician asks an MSL about an off-label use during a scientific exchange.

Speaker	Line
Physician	Have you seen data for use in younger patients?
MSL	That is outside the approved indication.
ESL learner	I can respond to your unsolicited scientific question with available data, but I need to be clear that this use is not approved. I cannot recommend off-label use, and I can provide medical information resources if you would like a formal response.
Physician	So you have data?
ESL learner	I can discuss the study design and limitations in a balanced way, including what is known, what is not known, and how it differs from the approved population.

Language notes

- Boundary language should be clear without shutting down legitimate scientific exchange.
- Balance and context matter in medical affairs conversations.

Role-play variation

Observer checklist

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10. Payer Evidence: Value Story Is Not the Same as Label

Setting

Market access is preparing for payer discussions after approval.

Speaker	Line
Market access	Payers will ask why this deserves preferred formulary status.
HEOR	We have clinical data but limited real-world outcomes.
ESL learner	The payer value story should connect eligible population, clinical benefit, safety, budget impact, comparator, adherence, and unmet need. We should not imply outcomes we have not measured.
Commercial	Can we say it reduces hospitalizations?
ESL learner	Only if the evidence supports that claim for the relevant population and context. Otherwise, we can frame it as a hypothesis or evidence-generation need.

Language notes

- Market access language must separate approved label, evidence, and economic hypothesis.
- Payer communication should avoid unsupported outcomes claims.

Role-play variation

Observer checklist

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11. Biosimilar Discussion: Similar Is Not Identical

Setting

A cross-functional team is preparing educational material on a biosimilar.

Speaker	Line
Commercial	Can we say it is the same as the reference product?
Regulatory affairs	Biosimilar language is more specific than that.
ESL learner	We should say highly similar with no clinically meaningful differences in safety, purity, and potency, consistent with the approved biosimilar framework. 'Same' may oversimplify and create confusion.
Medical affairs	What about interchangeability?
ESL learner	Interchangeability has a specific regulatory meaning. We should use it only if the product has that designation and the material explains it accurately.

Language notes

- Biosimilar language needs regulatory precision.
- Avoid simplifying technical terms into misleading equivalence.

Role-play variation

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12. Launch Readiness: Approval Is Not Enough

Setting

The team is two months from expected approval and launch readiness is uneven.

Speaker	Line
General manager	If approval comes on time, we launch immediately.
Launch lead	Supply, MLR materials, medical training, payer coverage, and PV intake process still have open risks.
ESL learner	Approval is necessary but not sufficient for launch. We need a readiness view across label, supply, quality release, safety reporting, medical information, field training, access, and promotional materials.
General manager	What is the critical path?
ESL learner	Supply release, final label-dependent MLR approval, safety intake readiness, and payer communication are the main dependencies. I recommend a weekly risk review until launch decision.

Language notes

- Launch readiness requires cross-functional dependency language.
- Approval timing should not hide supply, safety, or compliance readiness risk.

Role-play variation

Observer checklist

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