EFSP Auxiliary ESL Curriculum

Pharmaceutical Jargon Field Guide

Quick reference for high-level ESL learners who need precise pharmaceutical vocabulary and cross-functional meeting language

Audience: advanced ESL learners in clinical development, clinical operations, regulatory affairs, pharmacovigilance, quality, CMC, manufacturing, medical affairs, market access, commercial compliance, and related roles

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 Use Pharmaceutical Jargon Well

- Use the term only when it clarifies evidence, patient safety, product quality, compliance, timeline, or decision ownership.
- Pair acronyms with plain English when speaking to cross-functional partners.
- Ask which document controls the answer: protocol, SAP, label, SOP, regulatory correspondence, quality record, or approved material.
- Avoid overclaiming efficacy, minimizing safety, bypassing quality disposition, or turning scientific exchange into promotion.

Nomenclature and Jargon

Teach these terms as working vocabulary. Learners should be able to define the term, use it in a realistic sentence, ask which regulation, protocol, SOP, label, quality record, or evidence standard applies, and explain the consequence for patients, data, product quality, or compliance.

Development strategy and regulatory path

Term	Working meaning
Indication	Disease, condition, or patient population for which a product is intended or approved.
MOA	Mechanism of action; how the product is understood to produce a biological effect.
TPP	Target product profile describing desired product attributes and evidence needs.
IND	Investigational new drug application allowing clinical investigation in humans in the United States.
NDA	New drug application requesting approval to market a drug.
BLA	Biologics license application requesting approval to market a biologic.
Accelerated approval	Approval pathway using a surrogate or intermediate clinical endpoint reasonably likely to predict clinical benefit.
Complete response letter	FDA communication that an application is not ready for approval in its current form.

Clinical trials and GCP

Term	Working meaning
Protocol	Document describing study objectives, design, population, assessments, endpoints, safety, and analysis.
Randomization	Assignment to treatment groups by chance to reduce bias.
Blinding	Keeping treatment assignment unknown to reduce bias.
Control arm	Comparator group used to interpret the effect of the investigational treatment.
Informed consent	Process and documentation showing that participants understand key trial information before participation.
Protocol deviation	Departure from the approved protocol or study procedures.
Risk-based monitoring	Monitoring approach focused on critical risks to participant safety and data reliability.
Data integrity	Completeness, consistency, accuracy, and reliability of data throughout the lifecycle.

Endpoints, statistics, and data interpretation

Term	Working meaning
Primary endpoint	Main outcome measure used to evaluate the primary objective.
Secondary endpoint	Additional outcome measure supporting other objectives.
Exploratory endpoint	Outcome assessed to generate hypotheses or additional insight, usually not definitive.
Estimand	Precise description of the treatment effect being estimated.
Intercurrent event	Event after treatment initiation that affects interpretation or existence of measurements.
P-value	Measure of compatibility between observed data and a null hypothesis under model assumptions.
Confidence interval	Range reflecting uncertainty around an estimate.
Sensitivity analysis	Analysis testing how robust results are to assumptions or data handling choices.

Safety and pharmacovigilance

Term	Working meaning
AE	Adverse event; unfavorable medical occurrence after product use, regardless of causality.
SAE	Serious adverse event meeting criteria such as death, life-threatening event, hospitalization, disability, or birth defect.
SUSAR	Suspected unexpected serious adverse reaction.
MedDRA	Medical Dictionary for Regulatory Activities used to code medical terms.
Case narrative	Written summary of an individual safety case.
Signal detection	Process for identifying information that may suggest a new or changed risk.
Risk-benefit	Integrated assessment of benefits, risks, uncertainty, disease severity, and alternatives.
REMS	Risk Evaluation and Mitigation Strategy used to manage serious known or potential risks when required.

CMC, CGMP, quality, and supply

Term	Working meaning
CMC	Chemistry, manufacturing, and controls information supporting product quality.
API	Active pharmaceutical ingredient.
Specification	Quality standard a material or product must meet.
Batch record	Documented record of manufacturing steps, controls, and results for a batch.
OOS	Out of specification result requiring investigation.
Deviation	Departure from approved procedure, process, specification, or expected result.
CAPA	Corrective and preventive action addressing root cause and recurrence prevention.
Process validation	Evidence that a manufacturing process consistently produces product meeting quality requirements.

Labeling, medical affairs, and promotion

Term	Working meaning
Prescribing information	Approved product information describing indication, dosing, warnings, adverse reactions, and other use information.

Term	Working meaning
Indication statement	Approved language describing what the drug is approved to treat and in whom.
Fair balance	Balanced communication of benefits and risks so the message is not misleading.
Off-label	Use or discussion outside approved labeling.
MLR	Medical, legal, and regulatory review of materials.
Promotional claim	Product-related statement intended to promote use and requiring support and compliance review.
Scientific exchange	Non-promotional scientific communication, usually handled within medical affairs boundaries.
Medical information	Function that responds to medical inquiries with approved, balanced, evidence-based information.

Market access, RWE, and lifecycle

Term	Working meaning
HEOR	Health economics and outcomes research.
Formulary	List of medicines covered or preferred by a payer or health system.
Prior authorization	Payer requirement for approval before coverage.
Step therapy	Payer rule requiring use of one therapy before another.
RWD	Real-world data routinely collected from health care or patient sources.
RWE	Clinical evidence about usage, benefits, or risks derived from RWD analysis.
Biosimilar	Biologic highly similar to a reference product with no clinically meaningful differences.
Lifecycle management	Post-approval strategy for evidence, indications, formulations, access, safety, and competition.

Common Meeting Moves

Development strategy and evidence

- What decision does this evidence support?
- The mechanism is promising, but the clinical value proposition is not yet clear.
- We should connect the endpoint to patient benefit, regulatory acceptability, and payer relevance.
- The TPP needs to specify population, comparator, dosing, safety assumptions, and differentiation.

Regulatory and clinical operations

- I would not describe this as agency agreement; it is regulatory feedback with remaining sponsor risk.
- The protocol may be scientifically rich but operationally burdensome.
- Before adding sites, we should understand screen failures, visit burden, and competing trials.
- This deviation needs impact assessment for participant safety, rights, and data integrity.

Data interpretation

- Statistical significance does not automatically mean clinical relevance.
- The subgroup is hypothesis-generating unless the analysis was pre-specified and adequately powered.
- The estimand clarifies what treatment effect we are actually estimating.
- We should present effect size, confidence interval, population, safety, and limitations together.

Safety and pharmacovigilance

- We should not jump to causality, but we also should not minimize the pattern.
- Let's assess seriousness, expectedness, relatedness, and reporting timeline.
- A signal means further evaluation is needed; it is not automatically a confirmed risk.
- The risk-benefit update should include severity, alternatives, reversibility, and mitigation.

Quality and manufacturing

- Supply pressure does not remove quality disposition requirements.
- The batch decision must be evidence-based, documented, and approved through the quality system.
- We need root cause, containment, CAPA, and recurrence prevention.
- The manufacturing change requires comparability evidence before we treat it as low risk.

Medical, promotional, and access boundaries

- The claim may be scientifically interesting but not promotional-ready.
- We need to confirm consistency with approved labeling and fair balance.
- I can answer an unsolicited scientific question, but I cannot recommend off-label use.
- The payer message should separate demonstrated outcomes from economic hypotheses.

Fast Contrast Pairs

Do not confuse	Working contrast
Adverse event vs adverse reaction	AE occurs after product use; adverse reaction implies reasonable possibility of causal relationship.
Serious vs severe	Serious is regulatory outcome-based; severe describes intensity.
Endpoint vs estimand	Endpoint is what is measured; estimand defines the treatment effect being estimated.
Statistical significance vs clinical relevance	Statistical result may be reliable but still modest or not meaningful for patients.
Signal vs confirmed risk	Signal suggests further evaluation; confirmed risk is supported by stronger evidence.
Deviation vs CAPA	Deviation is what went wrong; CAPA addresses root cause and recurrence prevention.
Scientific exchange vs promotion	Scientific exchange is balanced and non-promotional; promotion encourages product use within approved boundaries.
RWD vs RWE	RWD is the data source; RWE is clinical evidence derived from analysis of that data.

Source Orientation

- FDA drug development and approval resources, including IND, NDA, and BLA pathway language.
- ICH E8(R1) and ICH E6(R3) guidance for clinical-study quality, GCP, participant protection, data reliability, and risk-proportionate trial conduct.
- ICH E9(R1) estimands and sensitivity-analysis guidance for endpoint, intercurrent-event, and treatment-effect language.
- FDA current good manufacturing practice resources for pharmaceutical quality, manufacturing controls, documentation, and quality-system language.

- FDA FAERS, MedWatch, IND safety reporting, and postmarketing adverse-event reporting resources for pharmacovigilance language.
- FDA OPDP and promotional labeling and advertising resources for claims, fair balance, promotional material submissions, and review language.
- FDA real-world evidence and biosimilar resources for RWD, RWE, reference product, biosimilar, and interchangeability language.
- The learner's own company SOPs, approved labeling, safety management plans, quality systems, regulatory correspondence, MLR process, and legal or compliance guidance.