EFSP Auxiliary ESL Curriculum

Medical Devices English Jargon Quick Reference

Field-specific terms, contrast pairs, and high-pressure sentence frames

Audience: medical device engineers, product managers, quality and regulatory staff, clinical specialists, manufacturing teams, field-service teams, and device-company leaders

Focus: A device-focused professional English curriculum for design controls, risk management, usability, verification and validation, regulatory pathways, complaint handling, quality systems, manufacturing, and clinical-user dialogue.

Designed for advanced ESL learners who already use professional English and need industry-specific terminology, realistic meetings, role-play pressure, careful pushback, and polished workplace outputs.

Teaching stance: this is language and workplace-communication training, not legal, medical, financial, safety, or regulatory advice. Instructors should connect every scenario to the learner's current company policies, local rules, and approved procedures.

Nomenclature and Jargon

These are classroom working definitions. Learners should adapt wording to their organization's policies, systems, and local regulatory environment.

User Needs and Design Inputs

Term	Working meaning
user need	Working medical devices term used in user needs and design inputs; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
design input	Working medical devices term used in user needs and design inputs; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
intended use	Working medical devices term used in user needs and design inputs; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
traceability	Working medical devices term used in user needs and design inputs; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Risk Management and Hazard Analysis

Term	Working meaning
hazard	Working medical devices term used in risk management and hazard analysis; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
harm	Working medical devices term used in risk management and hazard analysis; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
FMEA	Working medical devices term used in risk management and hazard analysis; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
residual risk	Working medical devices term used in risk management and hazard analysis; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Verification, Validation, and Design Review

Term	Working meaning
verification	Working medical devices term used in verification, validation, and design review; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
validation	Working medical devices term used in verification, validation, and design review; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
design review	Working medical devices term used in verification, validation, and design review; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
acceptance criteria	Working medical devices term used in verification, validation, and design review; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Usability and Human Factors

Term	Working meaning
human factors	Working medical devices term used in usability and human factors; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
use error	Working medical devices term used in usability and human factors; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Term	Working meaning
formative study	Working medical devices term used in usability and human factors; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
summative study	Working medical devices term used in usability and human factors; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Regulatory Pathways and Submissions

Term	Working meaning
510(k)	Working medical devices term used in regulatory pathways and submissions; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
De Novo	Working medical devices term used in regulatory pathways and submissions; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
PMA	Working medical devices term used in regulatory pathways and submissions; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
predicate device	Working medical devices term used in regulatory pathways and submissions; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Complaints, MDRs, and Postmarket Signals

Term	Working meaning
complaint	Working medical devices term used in complaints, mdrs, and postmarket signals; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
MDR	Working medical devices term used in complaints, mdrs, and postmarket signals; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
malfunction	Working medical devices term used in complaints, mdrs, and postmarket signals; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
postmarket surveillance	Working medical devices term used in complaints, mdrs, and postmarket signals; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Manufacturing, Suppliers, and Nonconformance

Term	Working meaning
nonconformance	Failure to meet a requirement, specification, contract, standard, or approved procedure.
supplier CAPA	Working medical devices term used in manufacturing, suppliers, and nonconformance; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
process validation	Working medical devices term used in manufacturing, suppliers, and nonconformance; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
lot traceability	Working medical devices term used in manufacturing, suppliers, and nonconformance; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Clinical Training and Labeling Boundaries

Term	Working meaning
labeling	Working medical devices term used in clinical training and labeling boundaries; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
instructions for use	Working medical devices term used in clinical training and labeling boundaries; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Term	Working meaning
off-label	Working medical devices term used in clinical training and labeling boundaries; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.
clinical evidence	Working medical devices term used in clinical training and labeling boundaries; define the owner, evidence source, governing document, risk, and decision impact before using it in a meeting.

Industry-Specific Meeting Moves

Situation	Useful language
User Needs and Design Inputs	Before we commit, I want to confirm user need, design input, the owner, and the evidence behind the decision. If user need, design input, intended use, and risk must be separated., I recommend we document the risk and agree on the next step.
Risk Management and Hazard Analysis	Before we commit, I want to confirm hazard, harm, the owner, and the evidence behind the decision. If severity, probability, detectability, and mitigation evidence need review., I recommend we document the risk and agree on the next step.
Verification, Validation, and Design Review	Before we commit, I want to confirm verification, validation, the owner, and the evidence behind the decision. If validation, usability, clinical workflow, and traceability may still be open., I recommend we document the risk and agree on the next step.
Usability and Human Factors	Before we commit, I want to confirm human factors, use error, the owner, and the evidence behind the decision. If interface design, labeling, workflow, and risk controls need assessment., I recommend we document the risk and agree on the next step.
Regulatory Pathways and Submissions	Before we commit, I want to confirm 510(k), De Novo, the owner, and the evidence behind the decision. If predicate comparison, indications, performance data, and agency review remain uncertain., I recommend we document the risk and agree on the next step.
Complaints, MDRs, and Postmarket Signals	Before we commit, I want to confirm complaint, MDR, the owner, and the evidence behind the decision. If complaint intake, adverse-event assessment, and reporting timelines may apply., I recommend we document the risk and agree on the next step.
Manufacturing, Suppliers, and Nonconformance	Before we commit, I want to confirm nonconformance, supplier CAPA, the owner, and the evidence behind the decision. If nonconformance, disposition, supplier capa, and process validation must be resolved., I recommend we document the risk and agree on the next step.
Clinical Training and Labeling Boundaries	Before we commit, I want to confirm labeling, instructions for use, the owner, and the evidence behind the decision. If labeling, intended use, clinical evidence, and compliance boundaries control the response., I recommend we document the risk and agree on the next step.

High-pressure pushback frames

- I understand the urgency. The risk is that we move faster than the evidence or process supports.
- I am not blocking the goal. I am naming the condition we need before the decision is safe and credible.
- If we accept this risk, we should name the owner, document the assumption, and define the trigger for escalation.
- That may be possible, but not under the current scope, timeline, or approval path.
- Let's separate what we know, what we assume, and what still needs confirmation.

Contrast Pairs

Do not confuse	Useful distinction
user need vs traceability	In user needs and design inputs, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.

Do not confuse	Useful distinction
hazard vs residual risk	In risk management and hazard analysis, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.
verification vs acceptance criteria	In verification, validation, and design review, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.
human factors vs summative study	In usability and human factors, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.
510(k) vs predicate device	In regulatory pathways and submissions, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.
complaint vs postmarket surveillance	In complaints, mdrs, and postmarket signals, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.
nonconformance vs lot traceability	In manufacturing, suppliers, and nonconformance, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.
labeling vs clinical evidence	In clinical training and labeling boundaries, define whether the discussion is about the current fact pattern, the controlling process, the stakeholder pressure, or the final decision.