EFSP Auxiliary ESL Curriculum

Medical Devices English

Instructor guide for advanced ESL learners working in medical devices

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.

Purpose and Course Logic

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.

Core language challenge

Advanced learners do not only need vocabulary. They need the ability to ask which standard applies, who owns the decision, what evidence is sufficient, what risk is being accepted, and how to disagree without sounding vague, defensive, or reckless.

Each module trains a realistic workplace pressure point with role-specific terms, decision language, pushback practice, and a written output learners can adapt to their own work.

Course objectives

- Use medical devices terminology accurately in meetings, written updates, handoffs, escalations, reviews, and client or stakeholder conversations.
- Turn vague requests into specific questions about evidence, owner, deadline, constraint, risk, and decision rights.
- Push back on unsafe, unsupported, noncompliant, unrealistic, or poorly scoped proposals while preserving professional trust.
- Handle realistic dialogues from the field, including conflict, uncertainty, documentation gaps, customer or stakeholder pressure, and cross-functional disagreement.
- Produce concise workplace outputs: briefing notes, escalation updates, meeting scripts, risk memos, decision records, and follow-up messages.

Instructor Module Plans

Module 1. User Needs and Design Inputs (90 minutes)

Translate user pain points into controlled requirements.

Learners should be able to

- Use these terms accurately: user need, design input, intended use, traceability.
- Explain the workplace tension: User need, design input, intended use, and risk must be separated.
- Respond professionally when a stakeholder says: Add it to the roadmap as requested.
- Draft a usable design-input clarification with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

A surgeon requests a feature after a product demo.

Add it to the roadmap as requested.

User need, design input, intended use, and risk must be separated.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.

4. Output lab: draft and revise a design-input clarification.

Module 2. Risk Management and Hazard Analysis (90 minutes)

Discuss hazards, harms, mitigations, and residual risk.

Learners should be able to

- Use these terms accurately: hazard, harm, FMEA, residual risk.
- Explain the workplace tension: Severity, probability, detectability, and mitigation evidence need review.
- Respond professionally when a stakeholder says: Document that the risk is low and move on.
- Draft a usable risk-control rationale with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

A team calls a rare use error acceptable.

Document that the risk is low and move on.

Severity, probability, detectability, and mitigation evidence need review.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.
4. Output lab: draft and revise a risk-control rationale.

Module 3. Verification, Validation, and Design Review (90 minutes)

Distinguish building the product right from building the right product.

Learners should be able to

- Use these terms accurately: verification, validation, design review, acceptance criteria.
- Explain the workplace tension: Validation, usability, clinical workflow, and traceability may still be open.
- Respond professionally when a stakeholder says: Say yes because verification passed.
- Draft a usable V&V readiness update with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

Leadership asks whether testing is finished.

Say yes because verification passed.

Validation, usability, clinical workflow, and traceability may still be open.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.

4. Output lab: draft and revise a V&V readiness update.

Module 4. Usability and Human Factors (90 minutes)

Explain use errors without blaming users.

Learners should be able to

- Use these terms accurately: human factors, use error, formative study, summative study.
- Explain the workplace tension: Interface design, labeling, workflow, and risk controls need assessment.
- Respond professionally when a stakeholder says: Call it a training problem.
- Draft a usable human-factors finding with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

A nurse repeatedly selects the wrong mode during formative testing.

Call it a training problem.

Interface design, labeling, workflow, and risk controls need assessment.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.
4. Output lab: draft and revise a human-factors finding.

Module 5. Regulatory Pathways and Submissions (90 minutes)

Use pathway language without promising clearance or approval.

Learners should be able to

- Use these terms accurately: 510(k), De Novo, PMA, predicate device.
- Explain the workplace tension: Predicate comparison, indications, performance data, and agency review remain uncertain.
- Respond professionally when a stakeholder says: Tell customers clearance is straightforward.
- Draft a usable regulatory pathway caveat with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

Sales wants to say clearance is guaranteed because predicates exist.

Tell customers clearance is straightforward.

Predicate comparison, indications, performance data, and agency review remain uncertain.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.

3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.
4. Output lab: draft and revise a regulatory pathway caveat.

Module 6. Complaints, MDRs, and Postmarket Signals (90 minutes)

Triage field reports with safety and regulatory discipline.

Learners should be able to

- Use these terms accurately: complaint, MDR, malfunction, postmarket surveillance.
- Explain the workplace tension: Complaint intake, adverse-event assessment, and reporting timelines may apply.
- Respond professionally when a stakeholder says: Handle it informally with the hospital.
- Draft a usable complaint intake summary with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

A field rep hears about a device malfunction during a case.

Handle it informally with the hospital.

Complaint intake, adverse-event assessment, and reporting timelines may apply.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.
4. Output lab: draft and revise a complaint intake summary.

Module 7. Manufacturing, Suppliers, and Nonconformance (90 minutes)

Communicate product-quality problems without hiding supply risk.

Learners should be able to

- Use these terms accurately: nonconformance, supplier CAPA, process validation, lot traceability.
- Explain the workplace tension: Nonconformance, disposition, supplier CAPA, and process validation must be resolved.
- Respond professionally when a stakeholder says: Use the parts to avoid backorder.
- Draft a usable supplier quality update with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

A supplier change caused dimensional variation.

Use the parts to avoid backorder.

Nonconformance, disposition, supplier CAPA, and process validation must be resolved.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.

2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.
4. Output lab: draft and revise a supplier quality update.

Module 8. Clinical Training and Labeling Boundaries (90 minutes)

Train users while staying inside cleared indications and instructions.

Learners should be able to

- Use these terms accurately: labeling, instructions for use, off-label, clinical evidence.
- Explain the workplace tension: Labeling, intended use, clinical evidence, and compliance boundaries control the response.
- Respond professionally when a stakeholder says: Demonstrate the technique to build enthusiasm.
- Draft a usable label-safe training response with facts, caveats, owner, and next step.

Customized scenario

Workplace pressure

A key opinion leader asks about an off-label technique.

Demonstrate the technique to build enthusiasm.

Labeling, intended use, clinical evidence, and compliance boundaries control the response.

Classroom sequence

1. Terminology drill: define each term, then use it in one sentence from the learner's own role.
2. Risk map: identify the stakeholder, the decision, the evidence gap, the operating constraint, and the cost of being wrong.
3. Pushback ladder: move from clarifying question to evidence-based objection to consequence to decision request.
4. Output lab: draft and revise a label-safe training response.

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.
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.
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.

Situation	Useful language
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.

Assessment and Coaching

Performance rubric

Skill	Developing	Proficient	Strong
Terminology	Recognizes terms but uses them loosely.	Uses field terms accurately in context.	Defines terms, connects them to evidence, and explains decision impact.
Pushback	Disagrees vaguely or avoids disagreement.	Names concern with evidence and next step.	Balances urgency, relationship, risk, owner, and decision rights.
Scenario judgment	Focuses on one stakeholder's preference.	Identifies constraint, risk, and process.	Guides the group toward a documented, realistic decision.
Written output	Writes general summaries.	Produces clear notes with facts and owner.	Creates concise, decision-ready workplace communication.

Source orientation

- Current FDA medical device and quality-system resources.
- Company design-control, complaint, and regulatory procedures.
- Approved labeling and instructions for use.
- The learner's own company policies, SOPs, contracts, systems, templates, and approved communication standards.