EFSP Auxiliary ESL Curriculum

Medical Devices English Participant Workbook

Practice pages for realistic field-specific meetings, pushback, documentation, and role-play preparation

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.

How to Use This Workbook

For each module, define the terms, identify the decision pressure, write a careful response, and practice the conversation aloud. Strong answers are specific, calm, evidence-aware, and tied to owner and next step.

Module 1. User Needs and Design Inputs

Situation

A surgeon requests a feature after a product demo.

Stakeholder pressure: Add it to the roadmap as requested.

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

Terms to use

- user need
- design input
- intended use
- traceability

Evidence, owner, or policy boundary

Pushback sentence

Draft the design-input clarification

Module 2. Risk Management and Hazard Analysis

Situation

A team calls a rare use error acceptable.

Stakeholder pressure: Document that the risk is low and move on.

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

Terms to use

- hazard
- harm
- FMEA
- residual risk

Evidence, owner, or policy boundary

Pushback sentence

Draft the risk-control rationale

Module 3. Verification, Validation, and Design Review

Situation

Leadership asks whether testing is finished.

Stakeholder pressure: Say yes because verification passed.

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

Terms to use

- verification
- validation
- design review

- acceptance criteria

Evidence, owner, or policy boundary

Pushback sentence

Draft the V&V readiness update

Module 4. Usability and Human Factors

Situation

A nurse repeatedly selects the wrong mode during formative testing.

Stakeholder pressure: Call it a training problem.

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

Terms to use

- human factors
- use error
- formative study
- summative study

Evidence, owner, or policy boundary

Pushback sentence

Draft the human-factors finding

Module 5. Regulatory Pathways and Submissions

Situation

Sales wants to say clearance is guaranteed because predicates exist.

Stakeholder pressure: Tell customers clearance is straightforward.

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

Terms to use

- 510(k)
- De Novo
- PMA
- predicate device

Evidence, owner, or policy boundary

Pushback sentence

Draft the regulatory pathway caveat

Module 6. Complaints, MDRs, and Postmarket Signals

Situation

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

Stakeholder pressure: Handle it informally with the hospital.

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

Terms to use

- complaint
- MDR
- malfunction
- postmarket surveillance

Evidence, owner, or policy boundary

Pushback sentence

Draft the complaint intake summary

Module 7. Manufacturing, Suppliers, and Nonconformance

Situation

A supplier change caused dimensional variation.

Stakeholder pressure: Use the parts to avoid backorder.

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

Terms to use

- nonconformance
- supplier CAPA

- process validation
- lot traceability

Evidence, owner, or policy boundary

Pushback sentence

Draft the supplier quality update

Module 8. Clinical Training and Labeling Boundaries

Situation

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

Stakeholder pressure: Demonstrate the technique to build enthusiasm.

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

Terms to use

- labeling
- instructions for use
- off-label
- clinical evidence

Evidence, owner, or policy boundary

Pushback sentence

Draft the label-safe training response

Capstone Simulation

Lead a cross-functional meeting in medical devices. Choose four modules from this workbook, connect the risks, and prepare a five-minute update with decision, evidence, constraint, owner, and next step.