EFSP Auxiliary ESL Curriculum

Medical Devices English Dialogue Lab

Realistic field-specific dialogues, role-play variations, and observer checklists

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.

Dialogue Practice Method

Read each exchange once for meaning, once for tone, and once for decision structure. Then replace the ESL learner line with a version from the learner's own workplace.

1. User Needs and Design Inputs

Setting

A surgeon requests a feature after a product demo.

Speaker	Line
Product manager	Add it to the roadmap as requested.
Design engineer	User need, design input, intended use, and risk must be separated.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm user need, design input, the owner, and the evidence standard before we commit.
Product manager	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short design-input clarification. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: user need, design input.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

2. Risk Management and Hazard Analysis

Setting

A team calls a rare use error acceptable.

Speaker	Line
Quality engineer	Document that the risk is low and move on.
R&D lead	Severity, probability, detectability, and mitigation evidence need review.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm hazard, harm, the owner, and the evidence standard before we commit.
Quality engineer	What would let us move forward without slowing everything down?

Speaker	Line
ESL learner	Let's document the assumption, define the risk trigger, and create a short risk-control rationale. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: hazard, harm.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

3. Verification, Validation, and Design Review

Setting

Leadership asks whether testing is finished.

Speaker	Line
Regulatory lead	Say yes because verification passed.
Engineering manager	Validation, usability, clinical workflow, and traceability may still be open.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm verification, validation, the owner, and the evidence standard before we commit.
Regulatory lead	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short V&V readiness update. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: verification, validation.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

4. Usability and Human Factors

Setting

A nurse repeatedly selects the wrong mode during formative testing.

Speaker	Line
Human-factors lead	Call it a training problem.
Clinical specialist	Interface design, labeling, workflow, and risk controls need assessment.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm human factors, use error, the owner, and the evidence standard before we commit.
Human-factors lead	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short human-factors finding. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: human factors, use error.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

5. Regulatory Pathways and Submissions

Setting

Sales wants to say clearance is guaranteed because predicates exist.

Speaker	Line
Regulatory affairs	Tell customers clearance is straightforward.
Sales director	Predicate comparison, indications, performance data, and agency review remain uncertain.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm 510(k), De Novo, the owner, and the evidence standard before we commit.
Regulatory affairs	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short regulatory pathway caveat. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: 510(k), De Novo.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

6. Complaints, MDRs, and Postmarket Signals

Setting

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

Speaker	Line
Field clinical specialist	Handle it informally with the hospital.
Complaint handler	Complaint intake, adverse-event assessment, and reporting timelines may apply.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm complaint, MDR, the owner, and the evidence standard before we commit.
Field clinical specialist	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short complaint intake summary. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: complaint, MDR.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

7. Manufacturing, Suppliers, and Nonconformance

Setting

A supplier change caused dimensional variation.

Speaker	Line
Supply-chain lead	Use the parts to avoid backorder.

Speaker	Line
Quality manager	Nonconformance, disposition, supplier CAPA, and process validation must be resolved.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm nonconformance, supplier CAPA, the owner, and the evidence standard before we commit.
Supply-chain lead	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short supplier quality update. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: nonconformance, supplier CAPA.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?

8. Clinical Training and Labeling Boundaries

Setting

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

Speaker	Line
Clinical trainer	Demonstrate the technique to build enthusiasm.
Surgeon	Labeling, intended use, clinical evidence, and compliance boundaries control the response.
ESL learner	I understand the goal, but we need to separate urgency from control. For this decision, I need to confirm labeling, instructions for use, the owner, and the evidence standard before we commit.
Clinical trainer	What would let us move forward without slowing everything down?
ESL learner	Let's document the assumption, define the risk trigger, and create a short label-safe training response. Then we can decide whether to proceed, escalate, or revise the plan.

Language notes

- The learner names the field-specific control point instead of giving a vague no: labeling, instructions for use.
- The response preserves the business goal while adding evidence, owner, and next-step discipline.

Role-play variation

Observer checklist

- Did the learner name the decision and the risk?
- Did the learner use at least two industry terms accurately?
- Did the learner give a concrete next step without overpromising?