CORE CONCEPT

Medical Disposables Manufacturing Course: Syringes, IV Sets, Gloves and Sterilisation Validation

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Introduction:

Medical disposables manufacturing, covering syringes, IV sets, gloves and sterilisation validation, is a 1-week course for moulding, extrusion, assembly, glove dipping, packaging, sterilisation and quality release teams in single-use device plants, ending with a Disposables Line Qualification and Sterilisation Validation Plan for a case plant. Plants lose lots when barrel flash, kinked tubing, glove pinholes and weak pouch seals go unnoticed, and when ethylene oxide or irradiation cycles lack evidence for release. Nominees already run, set up or test lines and learn through inspection walkthroughs of case lines and cycle records. CoreConcept Training Center delivers this medical disposables course.

Course Objectives:

- Explain how syringes, IV sets and examination gloves are built from polypropylene, PVC or polyolefin tubing, latex and nitrile, and where each process creates defects
- Set injection moulding, tubing extrusion and automated assembly parameters for syringe barrels, plungers and IV set components inside ISO 14644 controlled zones
- Run latex and nitrile glove dipping lines from former cleaning to leaching, curing, chlorination and pinhole water-leak testing
- Verify pouch and blister seal strength and package integrity for terminally sterilised products against ISO 11607
- Validate ethylene oxide cycles under ISO 11135 and radiation doses under ISO 11137, using ISO 11737 bioburden data and ISO 10993-7 residual limits
- Produce a Disposables Line Qualification and Sterilisation Validation Plan for a case plant

Target Audience:

- Production teams responsible for running injection moulding cells, tubing extruders and automated syringe or IV set assembly machines
- Glove dipping line teams responsible for compounding, former handling, curing ovens and stripping stations
- Process engineering teams responsible for equipment qualification, line trials and parameter windows
- Sterilisation teams responsible for ethylene oxide chambers, aeration rooms or irradiation contract processing
- Quality teams responsible for in-process inspection, bioburden sampling, residual testing and lot release
- Packaging teams responsible for pouch sealing, blister forming and labelling of sterile single-use products

Course Outline:

Day 1: Single-Use Device Families, Materials and Plant Baseline

- Syringe Barrel, Plunger, Gasket and Needle Hub Anatomy
- IV Set Spike, Drip Chamber, Roller Clamp and Luer Layout
- Polypropylene, PVC, Natural Latex and Nitrile Material Selection
- ISO 13485 Process Map From Resin Receipt to Lot Release
- Plant Baseline Review Using Scrap, Rework and Complaint Logs

Day 2: Moulding, Extrusion, Assembly and Glove Dipping Processes

- ISO 14644 Cleanroom Zoning for Moulding and Assembly Halls
- Multi-Cavity Injection Moulding Window for Syringe Barrels
- Medical Tubing Extrusion Sizing, Kink Resistance and Bonding
- Automated Assembly Stations With Silicone Dosing and Vision Checks
- Glove Former Coagulant Dipping, Leaching, Curing and Chlorination

Day 3: Packaging Seals, Bioburden and Sterilisation Method Selection

- ISO 11607 Pouch and Blister Seal Strength Testing
- Dye Penetration and Bubble Leak Package Integrity Tests
- ISO 11737 Bioburden Sampling Plan and Recovery Efficiency
- Ethylene Oxide Versus Gamma Versus Electron Beam Selection Matrix
- Sterility Assurance Level Targets for Single-Use Product Families

Day 4: Ethylene Oxide and Radiation Validation, Residuals and Release Risks

- ISO 11135 Preconditioning, Exposure and Aeration Qualification Runs
- ISO 10993-7 Ethylene Oxide and ECH Residual Testing
- ISO 11137 Dose Setting, VDmax Substantiation and Dose Audits
- Irradiation Dose Mapping and Polymer Discolouration Limits
- Glove Pinhole AQL Failures and Sterile Lot Rejection Cases

Day 5: Inspection Walkthrough and the Line Qualification Plan

- Case Moulding Cell and Dipping Line Walkthrough Checklist
- Case Ethylene Oxide Load Pattern and Cycle Record Challenge
- Case Dosimetry Report and Product Family Grouping Review
- Case Batch Release Dossier Gap Log and Corrective Actions
- Disposables Line Qualification and Sterilisation Validation Plan Completion

Skills You Will Gain:

- Moulding Window Setting
- Tubing Extrusion Control
- Glove Dipping Line Troubleshooting
- Seal Integrity Testing
- Bioburden Data Interpretation
- Ethylene Oxide Cycle Qualification
- Radiation Dose Substantiation
- Sterile Lot Release Review

Why Attend This Course:

- Deliver a Disposables Line Qualification and Sterilisation Validation Plan to the plant manager and the quality head for approval
- Decide whether a residual result, dose audit failure or seal defect requires a lot hold, requalification or a change of sterilisation method
- Avoid scrapped lots, failed customer audits and delayed tenders caused by missing moulding, dipping or sterilisation evidence
- Hand set-up sheets, dipping line checklists, seal test records and cycle review templates to shift crews and laboratory staff

Conclusion:

Back at the plant, the participant hands the plant manager, quality head and sterilisation lead a Disposables Line Qualification and Sterilisation Validation Plan covering moulding and extrusion windows, glove dipping controls, seal test limits, bioburden sampling, ethylene oxide cycle and radiation dose evidence and release criteria. Management uses it to decide which lines to requalify first, whether to keep or switch the sterilisation route and where test budgets go. After the first released lots under the plan, the team should compare scrap, residual results, dose audits and complaints with targets and adjust the weakest controls.

Frequently Asked Questions FAQ:

What should participants know before a medical disposables manufacturing course on syringes, IV sets, gloves and sterilisation validation?

Participants should already run, set up, test or release products on a moulding, extrusion, assembly, dipping or sterilisation line and read batch records. No engineering degree is needed. Bringing anonymised scrap data, seal test results or cycle records helps apply the walkthroughs to their own plant.

How does medical disposables manufacturing differ from a sterile pharmaceutical filling or hospital sterile services course?

It covers making and terminally sterilising single-use devices: moulding, extrusion, assembly, glove dipping, packaging seals, ethylene oxide and radiation validation and lot release. Pharmaceutical filling courses cover aseptic filling of liquids, and hospital sterile services courses cover reprocessing reusable instruments, neither of which this course addresses.

Why do medical disposables manufacturing plants use ethylene oxide for many syringes and IV sets?

Ethylene oxide sterilises heat-sensitive plastics without melting or warping them and reaches inside packed devices. It needs controlled preconditioning, exposure and aeration, and residual ethylene oxide and ECH must be tested before release because the gas is toxic.

What do participants take back from the medical disposables manufacturing course?

Participants take back a Disposables Line Qualification and Sterilisation Validation Plan for a case plant, with a moulding set-up sheet, dipping line checklist, seal test record, bioburden sampling plan and cycle review template to adapt to their own lines.