

NORMEC MTL · TRAINING

Pharmaceutical engineering and GMP training

From the people who do the work.

Twelve courses | Remote or in person | Tailored to your site



Ensuring the best quality
and safety, everywhere

Training from the people who do the work

Normec MTL runs twelve courses for sterile and pharmaceutical manufacturers, covering engineering, sterilisation, contamination control, qualification and risk.

Our lived experience becomes knowledge for your team.

Everything we teach comes from work we have done on sites. What we learn solving problems on live projects goes straight into the courses, so your people get what has worked in practice, not theory.

Why train with us

Case studies from live projects. Each course uses real problems we have solved, such as wet loads, steam quality failures, biofilm and failed qualifications. People recognise their own site in them.

Tailored to your site. Sessions are built around your loads, autoclaves, water system, cleanroom design and the issues you are dealing with now, not a generic agenda.

We have trained regulators around the world. We have delivered training to inspectors from the UK (MHRA), Ireland, the Netherlands, Italy, Brazil and China. When China's FDA introduced new GMPs in 2011, our Principal Consultant was asked to deliver the training and to write the inspection guide for the Chinese inspectorate.

A current view of inspections. Every course closes with the latest regulatory feedback and inspection trends, so the people you train know what inspectors are finding now.

How training is delivered

Our training is built around discussion rather than slides read aloud. Attendees work through real problems with the lecturer, ask questions as they go, and apply each topic to their own site. Where the equipment is available, practical sessions are hands-on. Courses are led by our subject matter experts or by our Principal Consultant, and everything below can be adjusted.

Format	Remote or in person. Most of our delivery is now remote, and most sites prefer it — see below.
Modules	Split into smaller modules, such as half days, so busy manufacturing teams can attend without leaving the line for long
Tailoring	Built around your own challenges and case studies, and lengthened or shortened to reach the level of detail and complexity your team needs
Certificates and notes	A certificate for every attendee at the end of the course, and full-colour notes to revisit the material afterwards
Packages and price	Education packages combine several courses, with custom assessments. Price is available on request

What attendees say

"I have worked with Mark as a great resource for consultation and training for 10 years or so... I have personally enjoyed and benefitted from several training sessions, and the training courses always receive positive feedback from colleagues."

Murraigh McDonald

Autoclave & Fermentation Pure Culture Engineer, Elanco

"The training facilitation is targeted at the right level with a balance of practical, interactive and didactic techniques. All the trainers are experts with ability to enthuse and educate delegates from engineers, operating and QC and even QA staff!"

Nick Batty

Quality & Compliance Training Manager, Health Protection Agency

"The case studies presented are so relevant to our current issues. Comforting to know the rest of the industry is struggling, even better to find out the solution to our current issues!"

Validation Engineer

Course attendee

"We have completed this 4 day SME training with SME level knowledge and a detailed action plan for the site."

Sterilisation course attendee

Sterile products site

Delivered remotely, where most sites now want it

The majority of our training is now delivered over Teams. That is not a compromise on the in-person course — it is what sites have asked for, for four practical reasons.

Cost	A significant saving on travel and expenses, which on a multi-day course for a full team is rarely a small number.
Sessions you can absorb	The course can be broken into half-day or single-day sessions delivered over several weeks, rather than booking your team out for three consecutive days.
Better retention	Learning outcomes improve when training is delivered in shorter, focused sessions. Attention and retention are better over a half day than over the third afternoon of a three-day block.
Sooner	We can usually start sooner. Finding one day a week for a period of weeks is easier than finding a whole week for travel and delivery.

In person, where it earns its place.

Some sessions are better on site, and we say so. Steam Quality Testing is hands-on at your own test point. Sterilisation training works well on site when the group is going to walk the autoclaves and work through your own cycle data. Where that is the right call, we deliver it that way.

What a remote course looks like

- The same lecturer, the same material and the same case studies as the in-person course
- Discussion-led, with attendees working through problems live rather than watching a presentation
- Built around your own loads, systems and current issues
- Full-colour notes and a certificate for every attendee, with optional knowledge checks and competency assessment where the training supports a qualification or requalification requirement

Our courses

Twelve courses in five pathways. Typical durations are shown, and every course can be shortened, split into modules or tailored to your site. A detailed programme for each course is available on request.

COURSE	WHAT IT COVERS	TYPICAL DURATION	LEVEL
FOUNDATION			
Introduction to Pharmaceutical Engineering	The unique challenges of engineering in a regulated environment, for engineers new to the industry.	2 days	Foundation
Sterile Product Manufacture	Every aspect of sterile manufacture, from microbiology and clean rooms to sterilisation and quality systems.	5 days	Foundation
ENGINEERING AND PROJECTS			
Pharmaceutical Engineering & GEP Trends	How Annex 15 and current trends change project engineering, qualification and requalification.	3 days	Intermediate
Critical Utilities	Water, steam, compressed air and process gases, and who owns their control.	2 days (up to 4)	Intermediate
High Purity Water Systems	Generation, storage and distribution, from raw water to point of use.	3 days	Intermediate
STERILISATION			
Sterilisation and Depyrogenation	Autoclaves, steaming in place, tunnels and ovens, taken to subject matter expert level.	2 to 4 days	Intermediate to SME
Advanced Sterilisation Validation	Cycle development, qualification and requalification for moist heat sterilisation.	3 days	Advanced
Steam Quality Testing	Hands-on testing of steam purity and physical properties, with competence signed off.	1 day	Practical
CONTAMINATION CONTROL AND INSPECTION			
Clean Room Technology	Design, air handling, environmental monitoring and qualification of the manufacturing environment.	3 days	Intermediate
Visual Inspection & Packaging of Parenteral Products	Manual, semi-automated and automated inspection, and how to qualify each.	2 days	Specialist
QUALIFICATION AND RISK			
Qualification of Thermal Systems	Qualifying and requalifying autoclaves, ovens, cold rooms, incubators and storage.	2 days	Specialist
Quality Risk Management	Risk assessment techniques, and keeping assessments live across the site.	2 days	Intermediate

Not sure which fits? Tell us the problem you are working on and we will recommend a course or a combination.

Training in practice

Two examples of what happens when a site trains with us.

STEAM QUALITY TESTING

A dryness failure that was not one

The ask. A pharmaceutical site's steam testing showed dryness value failures, with readings around 0.92 against a limit of 0.95, which pointed to wet steam. No wet autoclave loads had ever been observed.

What we did. The site's team attended our one-day Steam Quality Testing course on site, at their own steam test point. The classroom session covered the physical properties of steam. In the practical session every attendee carried out each test hands-on, including the dryness test.

The outcome. It showed that the site's contractor had been using the wrong set-up for the dryness test, with an uninsulated sample line that let the steam cool before it was measured. That had been producing false failures. Repeated with the correct set-up, the steam met the limit. The site is now taking control of the testing.

STERILISATION AND DEPYROGENATION

From four days of training to a site action plan

The ask. A sterile products site had recurring wet loads on its porous load autoclaves for around two years. To compensate it was running long drying phases, which cost throughput.

What we did. We delivered four days of subject matter expert level training on site, tailored to the site's own loads and autoclaves. The group worked through the site's real cycle data. The training ended with a detailed action plan for the site.

The outcome. The client described it as giving them SME-level knowledge and a plan for process improvements in efficiency and for solving long-standing problems. The wet loads stopped, and the drying phase was shortened by about 20 minutes per cycle.

Tell us the problem you are working on and who needs to attend, and we will recommend a course or a combination.

Where a team needs more than one course, we can build an education package with custom assessments. Price is available on request.

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