Pharmacy Aseptic Compounding and Cytotoxic Services Management

3 days | 21 training hours | 08:30 to 16:45 daily | 23 scheduled dates

Hospitals preparing intravenous admixtures and cytotoxic doses need tightly controlled aseptic services to protect patients and staff. This course covers cleanroom management, aseptic technique governance, cytotoxic handling and quality assurance for pharmacy compounding units. It is aimed at African hospital pharmacies building or improving safe preparation services.

Course objectives

This programme builds the practical capability to plan, control and evaluate the work it covers, to a standard the delegate's own organisation can rely on. By the end of the 3 days, delegates should be able to:

- Establish governance for aseptic and cytotoxic compounding services.
- Manage cleanroom classification, monitoring and cleaning routines.
- Oversee aseptic technique validation and operator competency.
- Implement safe handling controls for cytotoxic preparations.
- Apply quality assurance and documentation for compounded products.
- Manage staff safety, spill response and waste from compounding.

Learning outcomes

On successful completion of the course, delegates will be able to:

- Establish effective governance structures for aseptic and cytotoxic compounding services.
- Develop procedures for cleanroom cleaning, disinfection and environmental monitoring.
- Establish systems for aseptic technique validation and operator competency assessment.
- Explain the principles of safe cytotoxic medicine preparation, handling and administration.
- Develop quality assurance and quality control systems for compounded preparations.
- Develop staff training and competency programmes for aseptic and cytotoxic services.
- Apply the principles of hazardous pharmaceutical waste segregation and disposal.
- Identify opportunities for continuous improvement and risk reduction in pharmacy compounding services.
- Explain the principles and requirements of pharmacy cleanroom design, classification and operation.
- Apply good practice for the aseptic preparation and manipulation of sterile medicines.
- Identify contamination risks in aseptic compounding and implement appropriate controls.
- Implement controls that minimise occupational exposure to hazardous medicines.
- Establish systems for documentation, traceability, batch records and incident reporting.
- Establish procedures for cytotoxic spills, accidental exposure and emergency response.
- Monitor service capacity, productivity, quality indicators and operational performance.

Who should attend

This course suits hospital pharmacists, pharmacy and chief pharmacists, aseptic services pharmacists, aseptic unit supervisors, cytotoxic services managers, oncology and clinical pharmacists involved in intravenous therapy, aseptic compounding technicians, pharmacy quality assurance officers and infection prevention and control professionals. It is also useful to hospital administrators responsible for pharmacy services, healthcare risk managers and occupational health staff, and to any team establishing a new aseptic or cytotoxic facility.

RECOMMENDED ENTRY LEVEL

Delegates should be pharmacy professionals or technical staff working in, or preparing to work in, a hospital pharmacy compounding environment. Practical experience of dispensing, sterile preparation or pharmacy operations is useful but a formal aseptic qualification is not required. Delegates should be familiar with their own institution's pharmacy policies, standard operating procedures and the regulatory requirements that apply to medicines preparation in their country.

Course modules at a glance

Module	Topic	Main competency
01	Aseptic services governance	Accountable governance of a compounding service
02	Cleanroom management and monitoring	Control of the compounding environment
03	Aseptic technique and validation	Validated and repeatable aseptic practice
04	Cytotoxic handling and safety	Safe preparation and handling of hazardous medicines
05	Quality assurance and documentation	Assured product quality and full traceability
06	Operator competency and training	Qualified operators kept in requalification
07	Spill response and waste handling	Emergency response and safe waste disposal
08	Service capacity and performance	Measured and managed service delivery
09	Integrated risk management	Systematic risk control across the service
10	Integrated case study and action planning	Applied service improvement planning

The 3 day programme

Each training day runs 08:30 to 16:45 with morning and afternoon breaks and a lunch break. Timings can be adjusted to suit an in house group or a client's shift pattern.

Day 1: Aseptic services governance, cleanrooms and aseptic practice

Time	Session	Key topics	Activity
08:30 to 09:00	Registration and introduction	Introductions, expectations, course overview, delegate experience of compounding services	Delegate introductions

Time	Session	Key topics	Activity
09:00 to 10:15	Module 1: aseptic services governance	Role of aseptic services in hospital pharmacy; types of sterile preparation; intravenous admixtures and parenteral medicines; high risk activities; patient safety; the interface between pharmacy, nursing and clinical services; governance structures and accountability	Group discussion on accountability in a compounding unit
10:15 to 10:30	Tea break		
10:30 to 11:30	Module 1 continued: establishing a safe compounding service	Policies, procedures and standard operating procedures; risk management and escalation; service governance committees; service planning; workflow design; personnel, equipment and consumables; segregation of activities; patient specific against batch preparation	Exercise: draft a governance framework for an aseptic pharmacy unit
11:30 to 12:30	Module 2: cleanroom principles, classification and operation	Purpose of controlled environments; cleanroom classifications; critical and supporting areas; pressure differentials; airflow; temperature and humidity; personnel and material flows; entry, exit and gowning; behaviour in the cleanroom	Walkthrough of a cleanroom layout and flow
12:30 to 13:15	Lunch		
13:15 to 14:15	Module 2 continued: environmental monitoring	Monitoring principles; air, surface and microbiological monitoring; non viable particle monitoring; monitoring frequency; alert and action levels; trend analysis; handling excursions	Interpreting a set of monitoring results and excursions
14:15 to 15:00	Module 2 continued: cleaning and disinfection	Cleaning principles; disinfectant selection and rotation; cleaning schedules; cleaning validation; cleaning records; equipment and work surfaces; managing cleaning failures	Exercise: build a cleanroom monitoring and cleaning schedule
15:00 to 15:15	Tea break		
15:15 to 16:15	Module 3: aseptic technique and manipulation	Sources of contamination; critical sites and critical surfaces; personnel related contamination; maintaining first air; syringe, vial and ampoule handling; transfer procedures; disinfection of components; common aseptic technique failures	Workshop: identify contamination risks in a preparation process
16:15 to 16:45	Module 3 continued: validation and day one review	Purpose of validation; initial and periodic validation; competency assessment; media fill principles; operator qualification; documentation of validation	Day one review and questions

WHAT DELEGATES TAKE AWAY FROM DAY 1

- A governance framework that names who is accountable for the compounding service.
- A working understanding of cleanroom classification, flows and pressure regimes.
- A monitoring and cleaning schedule with alert and action levels.
- The ability to spot the contamination risks that aseptic technique is designed to control.

Day 2: Cytotoxic services, quality assurance and operator competency

Time	Session	Key topics	Activity
08:30 to 09:00	Day one recap	Review of governance, cleanroom control and aseptic technique	Question and answer session
09:00 to 10:15	Module 4: hazardous medicines and cytotoxic preparation areas	What makes a medicine hazardous; common cytotoxic medicines; routes of occupational exposure; patient and staff safety; risk assessment; facility requirements; dedicated preparation areas; engineering and containment controls; airflow and pressure; personnel and material movement	Risk assessment of a cytotoxic preparation area
10:15 to 10:30	Tea break		
10:30 to 11:45	Module 4 continued: safe handling, protective equipment and exposure	Receipt, storage, preparation, labelling and transport; the administration interface; handling contaminated materials; selecting protective equipment; donning and doffing; gloves, clothing, eye, face and respiratory protection; disposal; preventive controls and response to accidental exposure	Practical: donning and doffing sequence review
11:45 to 12:30	Module 4 case study	A cytotoxic preparation incident reviewed against the control system that should have prevented it	Case study: identify the control failures
12:30 to 13:15	Lunch		
13:15 to 14:15	Module 5: quality management and documentation	Quality assurance against quality control; quality management systems; risk based quality management; process and product controls; standard operating procedure management; master preparation records; worksheets; batch, cleaning, monitoring, equipment and training records	Review of a batch documentation set
14:15 to 15:00	Module 5 continued: traceability, deviations and CAPA	Patient specific preparations; batch numbers; raw materials; personnel and equipment; preparation and release records; expiry and beyond use dating; identifying, documenting and investigating deviations; root cause analysis; corrective and preventive action	Exercise: investigate a deviation and draft a CAPA plan
15:00 to 15:15	Tea break		
15:15 to 16:00	Module 5 continued: auditing and continuous improvement	Internal audits; quality indicators; trend analysis; audit findings; corrective action plans; effectiveness monitoring; continuous improvement	Building an internal audit checklist
16:00 to 16:45	Module 6: operator competency and training	Defining operator competencies; initial training; supervised practice; competency assessment; requalification and periodic reassessment; training in aseptic technique, cleanroom behaviour, cytotoxic handling, protective equipment, cleaning, spill management and documentation	Discussion of recurring competency gaps

WHAT DELEGATES TAKE AWAY FROM DAY 2

- A clear view of the controls that keep cytotoxic preparation safe for staff and patients.
- A documentation and traceability set that stands up to audit.
- A deviation investigation and CAPA plan produced from a real scenario.
- The outline of a competency framework for compounding personnel.

Day 3: Spill response, waste, service performance and improvement

Time	Session	Key topics	Activity
08:30 to 09:00	Day two recap	Review of cytotoxic controls, quality systems and competency management	Question and answer session
09:00 to 10:00	Module 6 continued: assessing operator performance	Observation based assessment; practical assessment; written knowledge assessment; media fill participation; recording and acting on assessment results	Workshop: build an operator competency checklist
10:00 to 10:15	Tea break		
10:15 to 11:15	Module 7: cytotoxic spill management and accidental exposure	Spill risk assessment; immediate actions; restricting access; spill kits and contents; protective equipment; safe clean up and decontamination; incident documentation; skin, eye and inhalation exposure; sharps incidents; reporting, escalation and occupational health follow up	Exercise: draft a cytotoxic spill response flowchart
11:15 to 12:15	Module 7 continued: hazardous pharmaceutical waste	Classification of pharmaceutical waste; cytotoxic waste segregation; sharps; contaminated protective equipment and consumables; temporary storage; internal transport; final disposal; labelling, waste tracking, contractor management and documentation	Waste segregation exercise
12:15 to 13:00	Lunch		
13:00 to 14:00	Module 8: service capacity, workflow and performance	Demand forecasting; workload assessment; staffing and shift planning; preparation scheduling; peak workloads; workflow mapping; reducing delays; managing urgent preparations; key performance indicators covering turnaround, rejected preparations, deviations, monitoring excursions, competency compliance and incidents	Selecting a small set of indicators for a compounding unit
14:00 to 14:45	Module 9: integrated risk management and safety culture	Patient, product, environmental, personnel, equipment and supply chain risk; risk evaluation and prioritisation; control measures and residual risk; incident escalation and investigation; lessons learned; reporting culture and leadership responsibilities	Risk prioritisation exercise
14:45 to 15:00	Tea break		

Time	Session	Key topics	Activity
15:00 to 16:00	Module 10: integrated case study	A hospital pharmacy service carrying a cleanroom monitoring failure, operator competency concerns, cytotoxic preparation risk, documentation gaps, waste management issues, staff exposure risk and capacity pressure	Group case study: identify risks, immediate actions and root causes
16:00 to 16:45	Action planning, final assessment and close	Preventive controls; monitoring indicators; the improvement action plan; final assessment; course review and close	Individual or group service improvement action plan

WHAT DELEGATES TAKE AWAY FROM DAY 3

- A spill response flowchart that can be posted in a compounding area.
- A waste segregation and tracking approach for hazardous pharmaceutical waste.
- A short set of indicators for monitoring capacity, quality and safety.
- A written improvement action plan for the delegate's own service.

How the course is taught

The programme is run as practical, competency based training rather than a series of presentations, so delegates rehearse the tasks they are expected to perform in their own working environment. Methods used include:

Facilitated presentations | Interactive discussions | Practical exercises | Group activities | Hospital pharmacy case studies | Governance framework development | Cleanroom monitoring and cleaning schedule exercises | Contamination risk identification workshops | Cytotoxic incident review | Deviation investigation and CAPA exercises | Operator competency checklist development | Spill response flowchart exercises | Waste segregation exercises | Knowledge checks | A final integrated case study and action plan

How delegates are assessed

Formative assessment

- Questions and discussions
- Short knowledge checks
- Group exercises
- Case studies
- Practical activities

Practical assessment

- Developing a governance framework for a compounding unit
- Building a cleanroom monitoring and cleaning schedule
- Identifying contamination risks in an aseptic preparation process
- Investigating a deviation and producing a CAPA plan
- Producing an operator competency checklist

- Producing a cytotoxic spill response flowchart

Final assessment

- Written knowledge assessment
- Integrated case study covering an aseptic and cytotoxic service
- Individual or group service improvement action plan

Certification

- Delegates who complete the required assessment activities receive a BMC Training certificate of completion for the programme.

Dates, venues and fees

The programme runs at 23 scheduled dates across the BMC Training network. Every date below is open for registration.

Dates	Venue	Days	Fee per delegate
28 to 30 Sep 2026	Nairobi	3 days	US$1,500
29 Sep to 1 Oct 2026	Dar es Salaam	3 days	US$1,500
30 Sep to 2 Oct 2026	Kigali	3 days	US$1,500
5 to 7 Oct 2026	Kampala	3 days	US$1,500
6 to 8 Oct 2026	Accra	3 days	US$1,500
7 to 9 Oct 2026	Lagos	3 days	US$1,500
12 to 14 Oct 2026	Cairo	3 days	US$1,500
13 to 15 Oct 2026	Mauritius	3 days	US$1,500
14 to 16 Oct 2026	Dubai	3 days	US$1,500
19 to 21 Oct 2026	Online	3 days	US$900
11 to 13 Nov 2026	Johannesburg	3 days	R13,000
16 to 18 Nov 2026	Cape Town	3 days	R13,000
17 to 19 Nov 2026	Durban	3 days	R13,000
18 to 20 Nov 2026	Pretoria	3 days	R13,000
23 to 25 Nov 2026	Windhoek	3 days	US$1,500
24 to 26 Nov 2026	Gaborone	3 days	US$1,500
25 to 27 Nov 2026	Maseru	3 days	US$1,500
30 Nov to 2 Dec 2026	Mbabane	3 days	US$1,500
1 to 3 Dec 2026	Lusaka	3 days	US$1,500
2 to 4 Dec 2026	Harare	3 days	US$1,500
7 to 9 Dec 2026	Lilongwe	3 days	US$1,500

Dates	Venue	Days	Fee per delegate
8 to 10 Dec 2026	Blantyre	3 days	US$1,500
9 to 11 Dec 2026	Mozambique	3 days	US$1,500

Fees are per delegate. South African venues are priced in rand; other locations and live online in US dollars. Fees exclude 15% VAT where applicable. Group bookings of three or more delegates from the same organisation qualify for a reduced rate. This course is also available as in house training, delivered at your own site on dates that suit your operation.

To book or request a quotation

Email registration@bmctrainings.org, WhatsApp +27 68 540 3736 or call +27 12 012 6265. Full course details and the live calendar are at www.bmctrainings.org.