Qualification Unit

This unit forms part of a regulated qualification.

Unit Title: Specials, Clinical Trials and Advanced Therapies Interface

Unit Reference Number: K/652/4186

Level: Five (5)

Credit Value: 5

Minimum Guided Learning Hours: 35

Learning Outcome (The Learner will):	Assessment Criterion (The Learner can):
1. Understand the regulatory frameworks governing Specials, investigational medicinal products and advanced therapy medicinal products	1.1 Evaluate the legal and regulatory requirements governing the manufacture and supply of Specials
	1.2 Compare Good Clinical Practice and Good Manufacturing Practice requirements applicable to investigational medicinal products
	1.3 Evaluate the regulatory classification and oversight of advanced therapy medicinal products
	1.4 Evaluate how regulatory differences between Specials, IMPs and ATMPs influence manufacturing arrangements, documentation and product release
2. Understand manufacturing and quality requirements for Specials, investigational medicinal products and advanced therapy medicinal products	2.1 Compare manufacturing and contamination control requirements for Specials, IMPs and ATMPs
	2.2 Evaluate the implications of small-batch, bespoke and patient-specific production for manufacturing process design
	2.3 Assess quality and product-handling risks associated with short shelf-life, temperature sensitivity and biological variability
	2.4 Evaluate manufacturing documentation and traceability controls used for Specials, IMPs and ATMPs

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3.	Be able to apply risk-based approaches to quality and patient safety within specialist pharmaceutical production	3.1	Apply Quality Risk Management principles to assess risks associated with Specials, IMPs or ATMPs
		3.2	Analyse the implications of material and product variability for manufacturing controls and product quality
		3.3	Evaluate deviations, out-of-specification or out-of-trend findings and their potential implications for product suitability
		3.4	Develop justified recommendations to address identified quality risks and support appropriate product decisions
4.	Be able to work effectively across multidisciplinary interfaces supporting Specials, IMP and ATMP production	4.1	Communicate technical and quality information to relevant clinical, research and pharmaceutical stakeholders
		4.2	Contribute to a multidisciplinary investigation or resolution of a technical or quality issue
		4.3	Evaluate multidisciplinary arrangements for managing patient-specific product logistics and traceability

Indicative Content	
LO1	1.1 must include the legal basis for manufacturing and supplying unlicensed medicinal products as Specials; applicable exemptions, licensing arrangements and MHRA expectations; implications for manufacture, quality assurance and supply. Other examples include Section 10 exemptions under the Medicines Act 1968 and manufacture under a Manufacturer's Specials Licence (MS). 1.2 must include the distinct purposes of GCP and GMP; clinical trial authorisation requirements; manufacture, packaging, labelling and supply of IMPs; Qualified Person (QP) certification where required; accountability and traceability; interfaces between manufacturing and clinical trial activities. Other examples include randomisation, blinding, unblinding procedures and management of clinical trial supplies. 1.3 must include the classification of gene therapy medicinal products, somatic cell therapy medicinal products and tissue-engineered products; relevant regulatory frameworks; manufacturing and quality requirements; implications of biological and patient-specific characteristics for regulatory oversight. Other examples include requirements arising from UK ATMP regulation, GMP expectations and relevant MHRA guidance. 1.4 must include comparison of regulatory requirements across the three product categories; implications for facility design, quality management systems, documentation, product traceability and release arrangements; responsibilities of appropriately authorised personnel. Other examples include batch manufacturing records, IMP dossiers, QP certification, chain of custody

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	and chain of identity.
LO2	2.1 must include manufacturing controls applicable to each product category; sterility assurance, aseptic processing and contamination control where relevant; environmental monitoring; equipment qualification; relationship between manufacturing arrangements, product characteristics and quality requirements. 2.2 must include production scale, product variability, individual patient requirements, scheduling and process flexibility; implications for manufacturing controls, verification, documentation and quality assurance. Other examples include bespoke Specials preparation, rapid-turnaround manufacturing, autologous and allogeneic ATMP workflows and patient-specific production schedules. 2.3 must include short shelf-life and stability considerations; temperature-controlled storage and transport; biological material variability; risks affecting product integrity, viability, availability and suitability for clinical use. Other examples include cold-chain management, cryopreservation, transport qualification or validation, and product-specific handling requirements. 2.4 must include batch manufacturing and processing records; product and material traceability; requirements for identifying, recording and tracking products throughout relevant manufacturing and supply stages; implications of incomplete or inaccurate records. Other examples include IMP accountability records, ATMP traceability logs, chain-of-identity records and chain-of-custody documentation.
LO3	3.1 must include identification and assessment of relevant quality and patient-safety risks; selection and application of appropriate QRM methods; evaluation of risk likelihood, severity and existing controls; justification of risk-reduction measures. Other examples include FMEA, HACCP and risk registers. 3.2 must include variability in raw materials, biological starting materials or patient-specific products; assessment of associated manufacturing and quality risks; implications for process controls and product suitability. Other examples include donor-specific characteristics, biological variability, cell viability, contamination risks and genetic or phenotypic changes where relevant. 3.3 must include interpretation of deviation and quality investigation evidence; OOS and OOT findings; assessment of potential implications for product quality, patient safety, product availability and clinical use; appropriate investigation and escalation requirements. 3.4 must include risk-based recommendations; appropriate corrective and preventive actions; consideration of product-specific requirements, patient safety and relevant regulatory controls; justification of recommendations using available evidence. Other examples include additional quality controls, process changes, investigation requirements, CAPA, product quarantine or escalation to authorised release personnel.
LO4	4.1 must include accurate and appropriate communication of technical information; consideration of stakeholder roles and information needs; communication of product requirements, quality concerns and operational constraints; documentation and escalation of relevant information. Other examples include communication with clinicians, research teams, production staff, quality control, quality assurance and regulatory personnel.

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	4.2 must include identification of relevant professional roles and responsibilities; contribution of technical information and evidence; collaboration in evaluating an issue; communication of findings and proposed actions; adherence to agreed responsibilities and escalation arrangements. Other examples include investigations involving deviations, complaints, manufacturing problems, product failures or supply disruptions. 4.3 must include coordination between manufacturing, quality, clinical and logistics functions; patient-specific scheduling and delivery requirements; product accountability; chain of identity and chain of custody where applicable; implications of communication or documentation failures for patient safety. Other examples include IMP supply to clinical trial sites, ATMP collection-to-administration pathways, temperature-controlled transport and management of time-critical deliveries.

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Assessment Requirements

Assessment must demonstrate the application of specialist knowledge and skills to the manufacture, quality management or supply of Specials, IMPs and ATMPs.

Learners must demonstrate Level 5 analytical and evaluative capability, including the ability to compare regulatory and manufacturing requirements, assess product-specific risks, interpret technical evidence and develop justified recommendations.

LO3 and LO4 require evidence of applied skills. Learners must demonstrate risk assessment, evidence-based decision-making, technical communication and contribution to multidisciplinary problem-solving.

Assessment may use authentic workplace activities or realistic scenarios supported by appropriate regulatory, manufacturing, quality and clinical information.

Learners are not required to have direct manufacturing experience across all three product categories. However, assessment must establish their understanding of the distinguishing requirements and risks associated with Specials, IMPs and ATMPs.

Learners are not required to make final clinical decisions, authorise product release, undertake Qualified Person responsibilities or act outside their professional scope.

The qualification does not confer occupational competence or professional authorisation in its own right.

Evidence may include:

- Comparative regulatory and manufacturing evaluations
- Technical reports on Specials, IMP or ATMP production requirements
- Quality risk assessments
- Evaluations of patient-specific manufacturing or supply arrangements
- Reviews of manufacturing documentation and traceability systems
- Deviation or quality investigation case studies
- CAPA recommendations
- Records of multidisciplinary meetings or technical discussions
- Technical communications prepared for clinical or research stakeholders
- Workplace projects and professional discussions supported by relevant evidence

LO1: Assessment should require learners to distinguish the regulatory requirements applicable to Specials, IMPs and ATMPs. Learners should evaluate their implications for manufacturing, documentation and release rather than simply describe each framework independently.

Particular care should be taken to ensure learners distinguish between the different legal arrangements for unlicensed medicines, clinical trial products and advanced therapies.

LO2: Learners should evaluate how product characteristics and manufacturing arrangements influence quality controls. Assessment should include comparison of at least two different production contexts, with sufficient evidence to demonstrate understanding of the distinct requirements across all three product categories.

Assessment should not require practical operation of every manufacturing system or

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direct experience of every product type.

LO3: Learners must apply a structured risk-based approach to a realistic technical or quality problem. Assessment should require interpretation of product or process evidence, consideration of patient-safety implications and development of justified recommendations.

A single integrated case study may address several criteria, provided the scenario contains sufficient complexity and relevant evidence.

LO4: Assessment must demonstrate the learner's ability to communicate technical information and contribute to multidisciplinary problem-solving.

Authentic workplace evidence may include meeting records, investigation contributions, handover documentation or technical communications. Where workplace opportunities are unavailable, realistic simulated activities may be used.

Professional discussion alone should not replace evidence of the learner actually undertaking the communication or collaborative activity required by AC 4.1 and 4.2.

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