Practical Guidance for Decentralized Manufacturing

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Why Decentralized Manufacturing (DM) and why now?

Manufacturing or testing activities conducted across multiple locations under coordinated oversight by a central product owner or authorised control site.

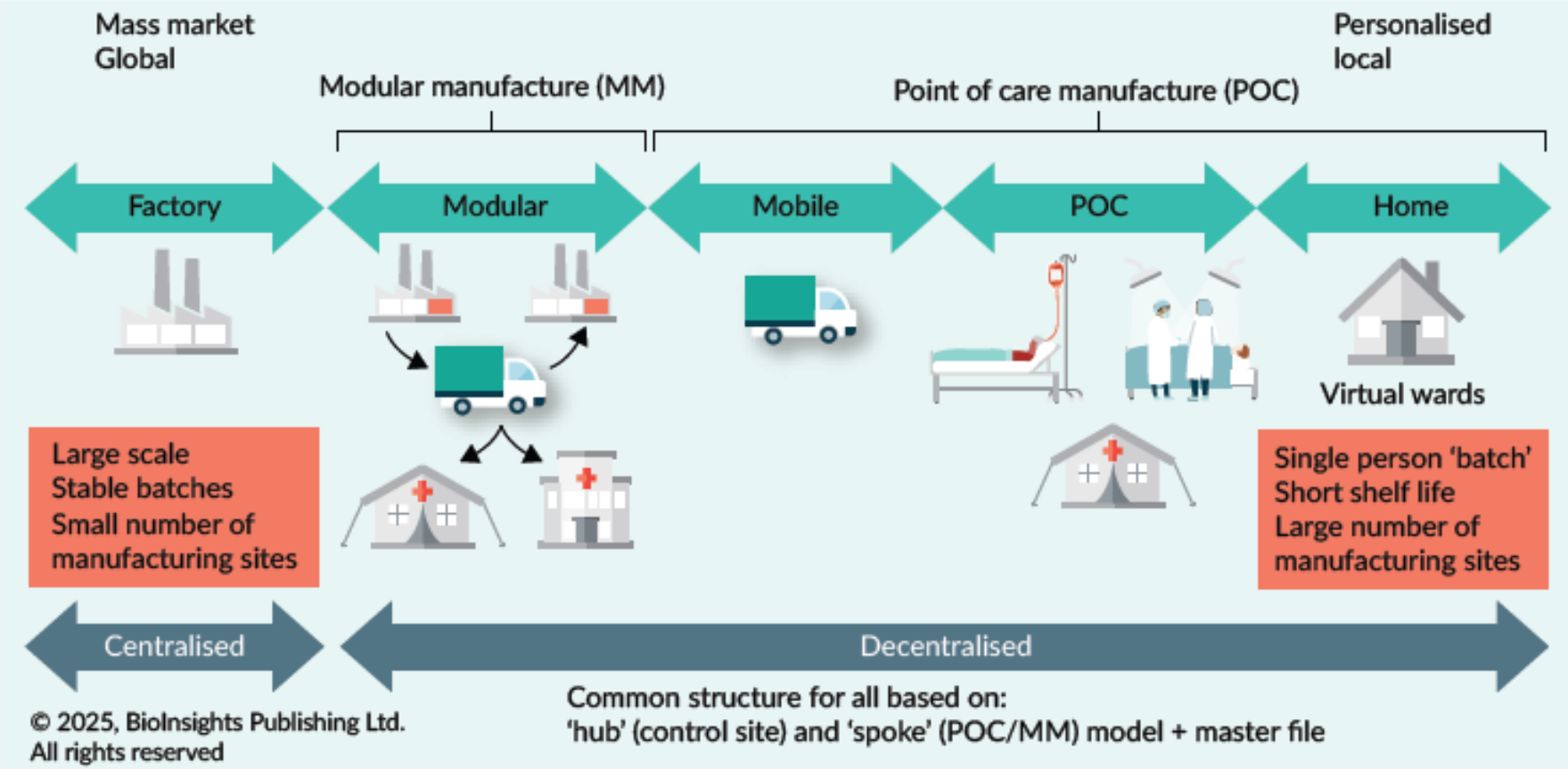
Potential Value

- Manufacture closer to collection and administration site
- Supports very short shelf-life and highly personalized products
- Can reduce transport, handling and supply-chain complexity
- Supports geographic access and on-demand capacity
- Creates options for rapid response and supply resilience

Enabling Capabilities

- Closed and increasingly automated processing systems
- Rapid or at-line analytical testing
- Electronic batch records and digital quality systems
- Remote process monitoring and expert oversight
- Accumulated process knowledge supporting risk-based decisions

A broadened spectrum of manufacturing and supply chain options.



- Different jurisdictions may use different legal terminology, but the underlying regulatory problem is the same: how to demonstrate consistent quality across a distributed network.

Global Regulatory Landscape

Europe	United Kingdom	United States
• Standard ATMP regulations apply • No specific decentralized manufacturing guidelines but expectation of manufacturing comparability, control strategy, process validation • Hospital Exemption framework • Upcoming EU Pharmaceutical Legislation Reform	• Dedicated Decentralized Manufacture hub and guidance • DM designation process • Hub-and-spoke model with Decentralized Manufacturing Master File	• Evaluating DM using existing GMP, CMC and product control principles • No dedicated DM guidance but vast practical experience • Specific cases typically addressed via IND interactions and Type B meetings • FDA Proposed Rule for Hub-and-Spoke

CERSI-AT Guidance on Decentralized Manufacturing

Published in *Cell & Gene Therapy Insights*, 2026

Purpose

Practical guidance developed through CERSI-AT. Uses the UK framework as a starting point, with wider relevance for global decentralized manufacturing.

Coverage

Quality, comparability, analytical testing, materials and network oversight.

Practical tools

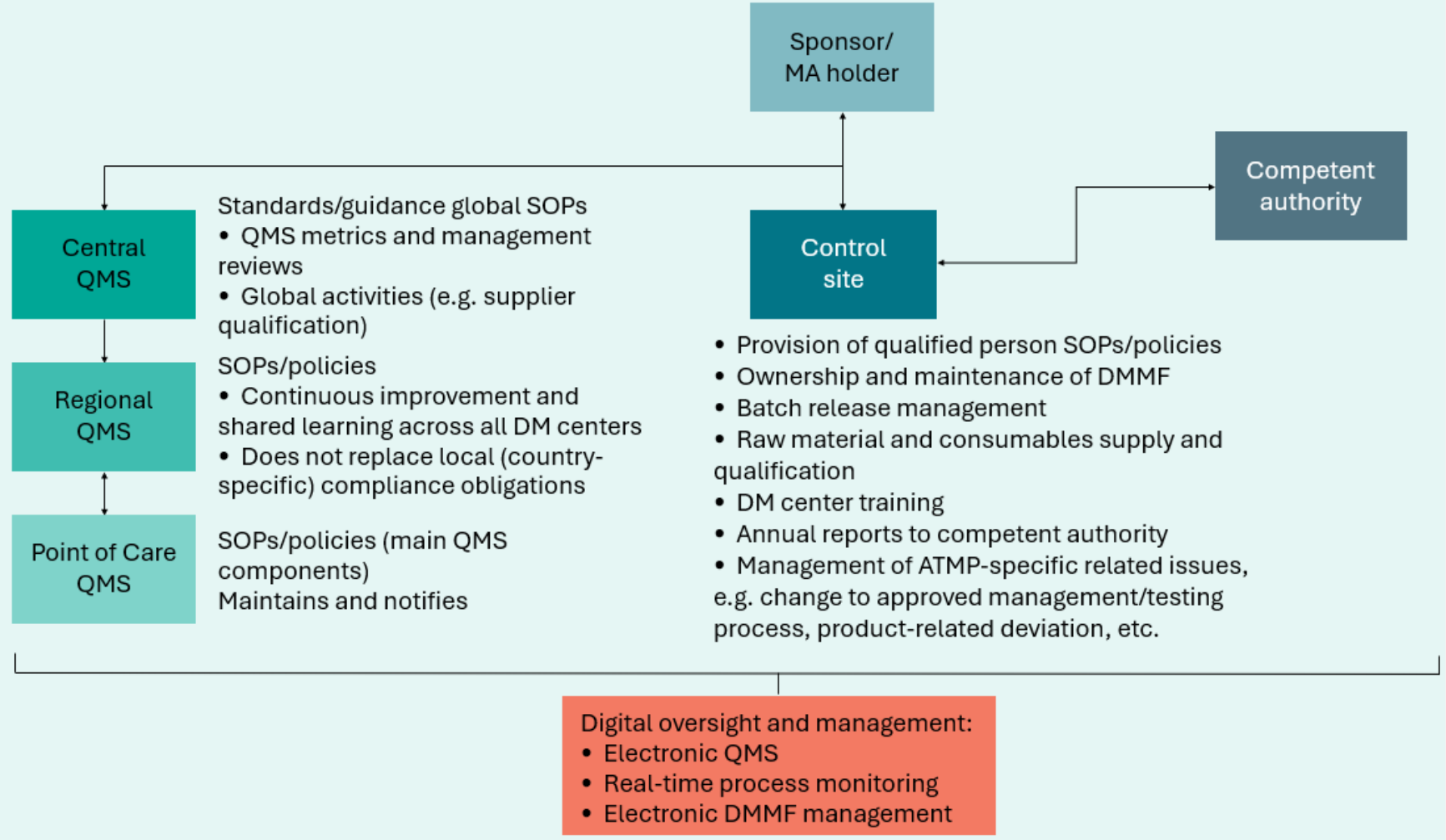
Illustrative case studies and challenge–mitigation tables.



Scan to read the paper

Supports developer decision-making, but is not formal regulatory guidance.

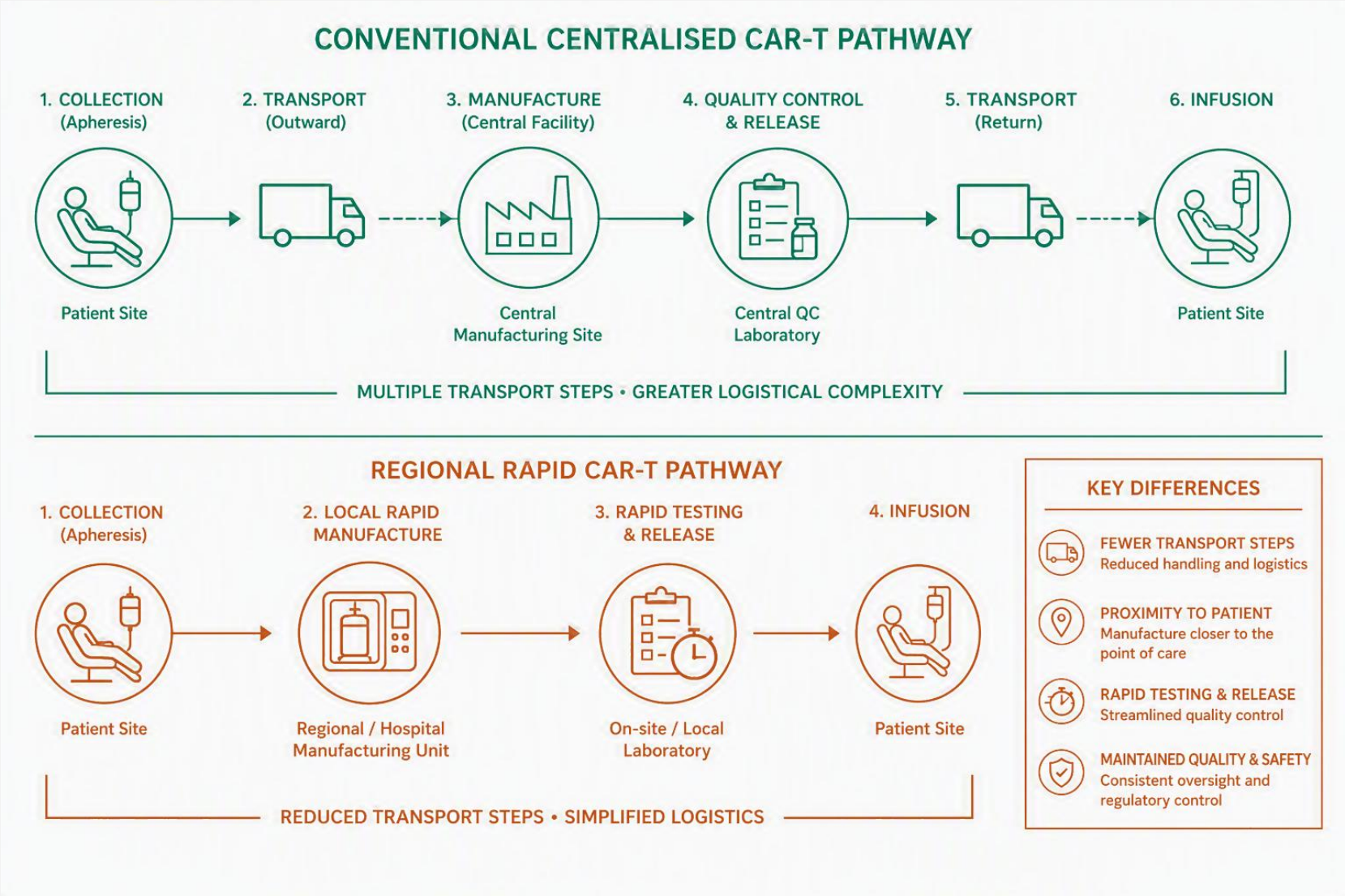
Global Operating Model: Centralized Control, Local Execution



One product owner coordinates the network; each site retains local accountability.

Case Study: Rapid CAR-T Manufacture

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Case Study: Rapid CAR-T Manufacture

CLINICAL BENEFIT

Shorter time from apheresis to administration.

MANUFACTURING REQUIREMENT

Closed or automated operation near the clinical site.

REGULATORY REQUIREMENTS

- Reliable process performance
- Rapid and validated testing
- Appropriate release arrangements
- Chain of identity and custody
- Comparable product across sites
- Robust escalation of out of specification batches

The Main Regulatory Challenges

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Product and Process Consistency

- CQAs and CPPs
- Process performance
- Site-to-site variability
- Platform equivalence

Materials and Supply

- Critical reagents and consumables
- Alternative locally available materials
- Supplier qualification
- Starting material variability

Analytical Control and Release

- Method transfer
- Rapid microbiology and potency testing
- Invalid and out-of-specification results
- Remote review and certification

Patient and Product Traceability

- Chain of identity
- Chain of custody
- Product-patient matching
- Pharmacovigilance and deviation reporting

Quality System and Digital Oversight

- Shared SOPs
- Training and competency
- Addressing deviations, CAPA and change control
- Data integrity and system availability

Comparability as the Regulatory Backbone

Between sites

Can a new site meet predefined criteria, ensuring process and product comparability?

Between platforms

Can the use of different equipment still ensure comparable CQAs?

Across the lifecycle

Can changes be introduced without loss of control across sites?

Potential Solutions

Product & process understanding

- Define CQAs, CPP relationships and design space early.
- Use risk-based acceptance criteria that account for material and batch variability.

Controlled network expansion

- Expand the site network in stages.
- Centralize material controls across sites where possible.

Comparability across the lifecycle

- Pre-plan comparability criteria and track trends across sites throughout the lifecycle.
- Learn from competitors, collaborators and early industry experience.

Rapid release & regulatory input

- Develop rapid release for fresh products with early regulatory input.
- Agree the evidence strategy with regulators early.

Integrated Control Strategy

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Ownership & governance

- Central accountability and control
- Qualified sites, suppliers and staff
- Change control and release oversight

Data & release

- Standardized digital records
- Real-time monitoring and testing
- Secure review and authorized release

Consistent Product Quality

Multi-site comparability

- Shared quality criteria
- Cross-site trending and verification
- Lifecycle and change assessment

Patient safety & traceability

- Identity, custody and patient matching
- Safety monitoring and escalation
- Recall readiness and data protection

Decentralised Manufacturing: What Comes Next

Manufacturing closer to patients requires comparable quality at every site.

Comparable quality

Agree site qualification criteria and track product quality across the network.

Global regulatory alignment

Countries and regulators need a shared strategy for site approval and evidence requirements.

Automation and AI

Pilot rapid testing and AI-assisted monitoring. Validate performance and retain human release oversight.

Next steps: a cross-border pilot with a shared comparability protocol.

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Delivering impact.

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