

Sneak Peek

CMC Regulatory Compliance for Biologics



Dr. Len Pattenden
CMC Expert and Independent
Consultant



SYMMETRIC

What Regulations are different or additional for mRNA?

From the consultation paper:

CMC considerations to emphasise:

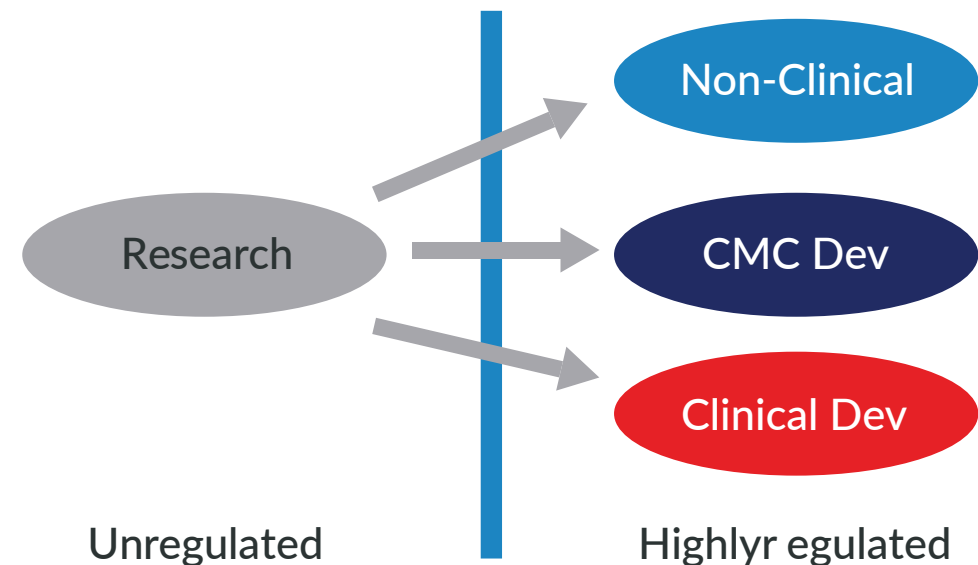
- Control starting materials (esp linear DNA template and plasmid DNA where relevant)
- Holistic **control strategy** from development to manufacture for the API, DS and DP
- Strong manufacturing control to ensure consistent quality, **based on relevant CAs**
- Characterisation approaches including **investigation of the impurity profile**
- **Purity control strategy**: process- and product-related, and potential contaminants (CCS)
- Active substance and finished product specifications
- **Potency testing**: different tests may be required to control various aspects of potency also including functionality (e.g. mRNA expression, protein expression in transduced cells)
- Details of **formulation strategies** - method of manufacturing of LNPs and their stability
- **Stability studies** for BOTH active substance and finished product

Holistic control strategy

Regulatory Precautions and compliance

- Higher scrutiny.
- The formulation will be heavily scrutinised in the CTD Module 3 (DS) esp choice of excipients.
- Key aspects of the manufacture and quality control that should be clearly defined:
 - starting material
 - active substance (DS/API?)
 - finished product intermediate (DS)
 - excipients
 - finished product (DP)

Key concept

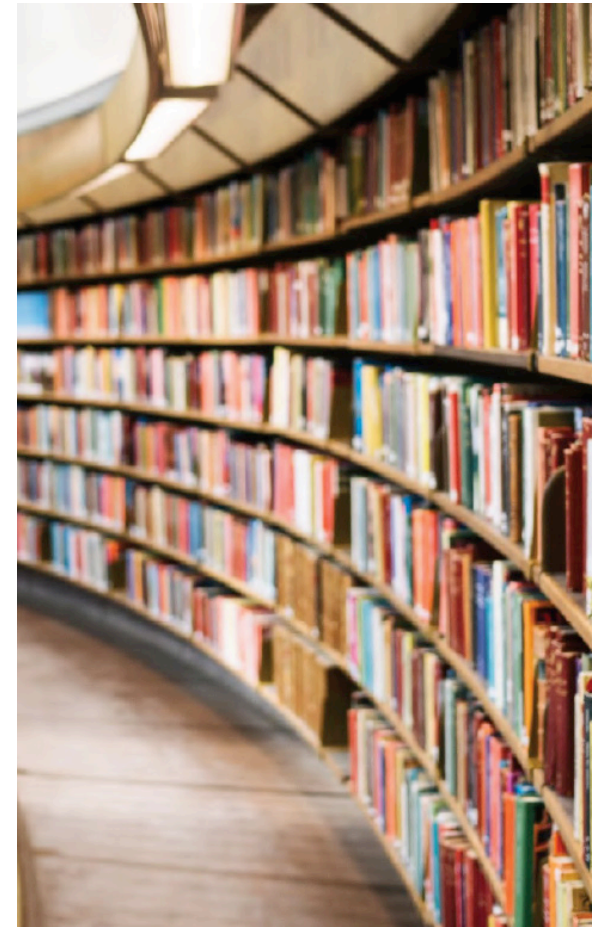


What Regulations are different or additional for ATMPs?

EMA specific guide for ATMPs is [here](#). (gene therapy) and cell therapy and tissue engineering are separated).

FDA specific guide draft for ATMPs is [here](#). Useful additional information and guidance explanations from the FDA are [here](#).

A position can be taken that the guidance is not really special or additional, but is enunciating biologics requirements and enforcing an annual review (continual improvement).



Regulatory Precautions and compliance

- An emphasis is made for:
 - PQS
 - Risk-based development
 - In-process control and testing (**especially where DP testing is lacking**)
 - Assessment and **control** of open-handling and “minimal processing”
 - Emphasis on materials specification, storage, shelf-life and testing GMP grade of materials
 - **Clamping down on** cell line history but...
 - **Safety must be understood and documented.**
 - **The passage number/stability understood.**
- Cell stocks should be GMP (**some stocks prior to Regulation 1394/2007 are non-GMP**)
- Automation/Pharma 4.0

Registration

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