Exercise 4: Set Up of Sterile Filtration

PDA
Parenteral Drug Association

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TRAINING

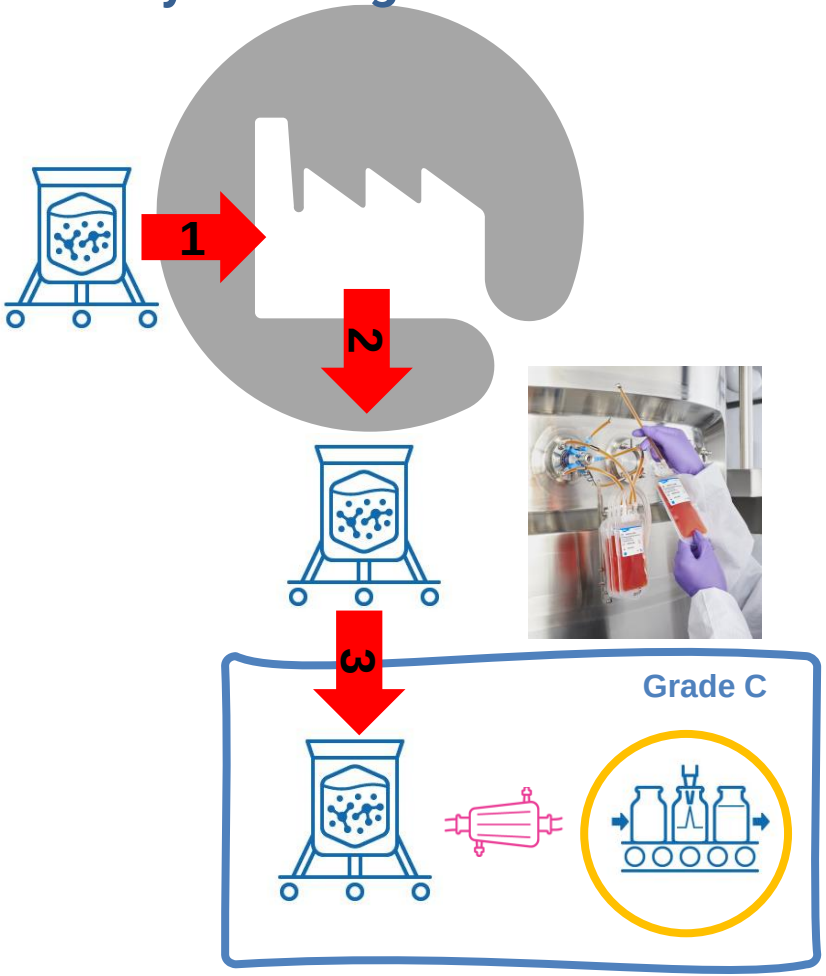
Session Content

- Best design practice: build your filtration set (Simone Biel)
    - 2 case studies will be discussed to build the appropriate filtration set-up
- Handling of sterile connection device to connect to the filling operation (Simone)
    - Every participant to practice a sterile connection
    - How does it work? (video)
- Handling of filtration process: wetting, flushing, filter integrity testing (Marco Klatte)
    - Live demo of the filtration process and best practice considerations

Build your filtration system

Case Studies

Case Study 1 – Large Batch Size

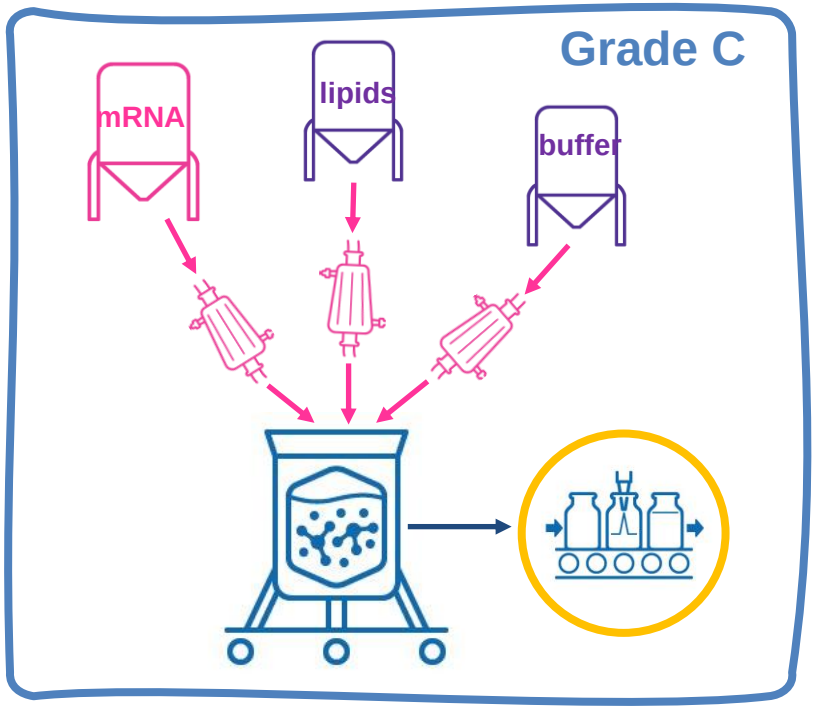


ParentiPharma is manufacturing monoclonal Antibodies. The final bulk drug product is filled into 200L closed stainless steel tanks, frozen, and shipped to the filling facility.

1) Reception and transfer to CNC area
2) Bioburden incoming control: sampling using a closed sampling system
   - ✓ bioburden is always below 10 cfu/100 ml
3) Transfer into Grade C cleanroom area
   - ✓ no further processing of the bulk before filtration
   - ✓ connection of the tank to the filtration set using a sterile connector to assure no change of bioburden level before filtration

- **Filtration characteristics of the product are well known**
- Historical experience: **never failed filter integrity test**
- **Annex 1 compliance required**
  - PUPSIT and post-use testing in line
  - bioburden sampling

Case Study 2 – Small Batch Size



LipidoGenix is manufacturing mRNA in LNP (lipid nano particles) in batch sizes of 10L.

- mRNA/LNP is an ATMP (Advanced Therapy Medicinal Product)
- Final product (in LNP encapsulated mRNA) cannot be filtered
- mRNA (active substance), lipids and buffers (excipients) are sterile filtered before encapsulation and formulation
- The product is very expensive and batch release right the first time is key
- Filtration studies have shown that the mRNA tends to block the filter

Considerations

- ATMP in scope of Annex 1?
- Active Substance in scope of Annex 1?
- Small batch size: PUPSIT or risk assessment?
- Redundant filtration: yes or no?