DECENTRALIZED MANUFACTURING AS THE FUTURE FOR CLINICAL TRIALS: A CASE STUDY

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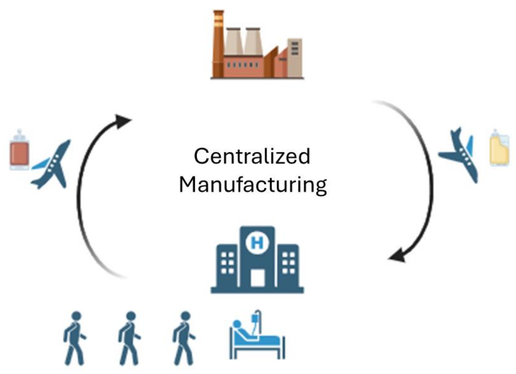
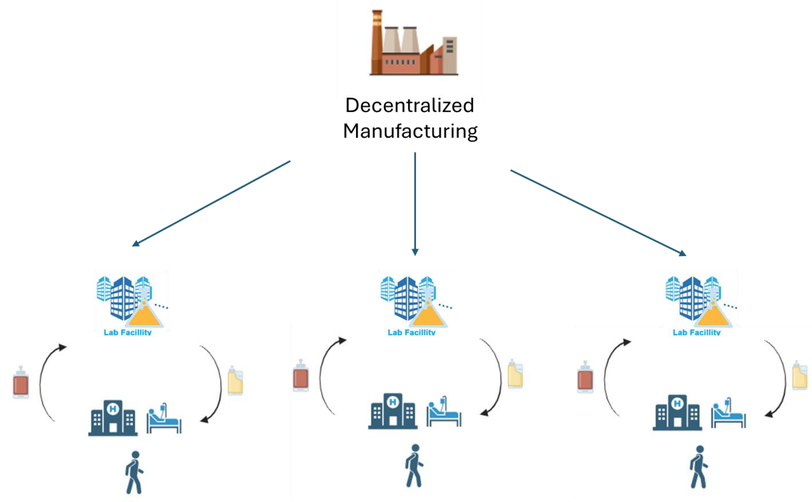
BACKGROUND



The **central manufacturing model** is based on a large-scale approach, in which drug production is limited to a single site and sent to hospital centers around the world via international transportation, resulting in a complex and expensive supply chain and in longer wait times for patient treatment.
Development toward **decentralized manufacturing**, that occurs locally and close to the site of patient treatment, has led to improved and expanded clinical trials to different countries with evolution of decentralized clinical trials (DCT) and has allowed the creation of **point-of-care (POC) units**.
POC units are a set of members included the manufacturing facility and hospital authorized for a clinical trials study.



OFFICINA FARMACEUTICA AS A MEMBER OF A POC UNIT

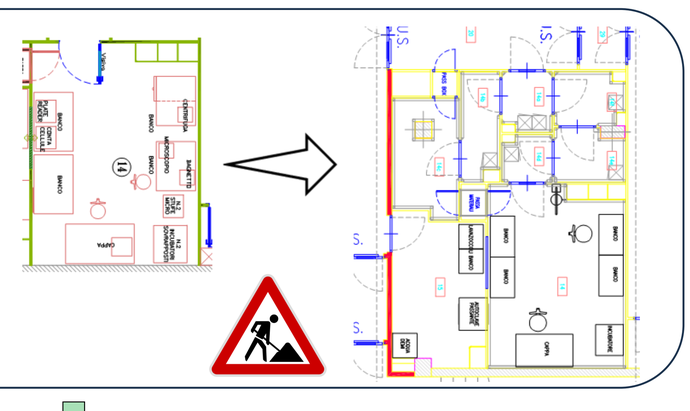
RECRUITMENT

Central Site

The Central Site recruits Officina Farmaceutica with the inspection visit of the facility and the establishment of the contract

REVAMPING

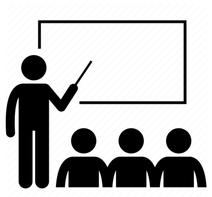
Officina Farmaceutica tailors the class B suite for gene therapy products manufacturing with the revamping of the facility followed by validation of the rooms and updating and implementation of related documents



AUDIT

Mutual Audit between POC unit members: Officina Farmaceutica, the Central Site and the Clinical Center

TRAINING



The Central Site provides the supply, installation, and training of instruments required for production and transfers methods and procedures to POC unit members

VALIDATION

Officina Farmaceutica must address Engineering run, Process Validation, and Aseptic Process Simulation

APPROVAL

National regulatory Authorities must approve the process in order to start the clinical trial

Recruitment and Contract → Revamping suite class B → Audit → Supply, Installation, and Training of Instruments; Transfer of the Methods → Engineering Run and Process Validation → Approval by National Regulatory

ADVANTAGES AND CHALLENGES

Central Site

Advantages:
- reduction of the supply chain complexity and scale production costs
- improvement of collected data (product, clinical) and data available in real time
- increased relationship with clinic centers

Challenges:
- POC comparability
- POC oversight (QMS, equipment management, training in/out, audit, overall control strategy)
- POC master file management and regulatory documentation

Officina Farmaceutica

Advantages:
- implementation of innovative technology
- enrichment of Operator's know-how
- proximity back-up sites (POC) and netwotking

Challenges:
- increase in document management, qualification and validation activities
- enforcement of country-specific regulations (GMO)
- critical vendor management (Central site)
- infrastructure readiness (revamping, essential change) and Operators

Clinical Center

Advantages:
- augmented patient recruitment
- implementation of networking with other clinical centers
- hospital team involvement on ATMP (pharmacist, nurse, clinician)

Challenges:
- increased management burden by the hospital

Patients

- **Only advantages for Patients**

CONCLUSIONS

In conclusion, the **decentralized model** is a challenge for the extension of clinical studies in different country and for engaging new manufacturing centers. For patients, it is an opportunity to have access to **personalized** and **innovative therapies**, especially for rare pathologies, and improved **patient monitoring** thanks to relationship with the clinical centers due to the **proximity to their house**. Overall, it has an important potential to speed up data collection and Market Access and to **improve patient's life**.