Webinar

The unexpected drivers of waste in clinical trial manufacturing

N-SIDE
OPTIMIZING YOUR DECISIONS

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Context - *In R&D manufacturing, Drug Substance, Drug Product and IMP lots are not fully allocated to patient demand, resulting in significant waste in the production process.*

N-SIDE, through its experience optimizing clinical programs, summarizes and clarifies the drivers of waste in clinical manufacturing.

Clinical manufacturing: a complex challenge

Minimizing waste

Avoiding risks

Average industry waste level reaches 85%

Based on all of the different programs/trials optimized each year by N-SIDE, **we were able to identify 4 main causes of drug waste in the manufacturing process:**

Inaccurate and variable demand

- Unreliable clinical data;
- Constantly evolving trial list;
- Increasing complexity of protocol design;
- Protocol amendments;
- Unsufficient planning accuracy;
- Uncertainties (pandemics, politics, etc.).

Constraints due to processes & resources

- Limited manufacturing resources & capabilities (minimum lot size, low production frequency, etc.);
- Complex supply chain with long manufacturing and shipping lead times;
- Development processes (unknown yield, stability plan, etc.);
- Lack of impact assessment of strategic decisions on waste and costs (stability plan, lot allocation constraints, scale up strategy, outsourcing strategy...).

Siloed decision making

- DS, DP and IMP planning managed by different teams facing conflicting objectives;
- Difficult to have a global view on the end-to-end clinical supply chain;
- Conflicting information may arise;
- Lack of data-driven alignment and decision making between teams;
- Lack of impact assessment of decisions in different teams regarding downstream waste.

Planning in a volatile environment

- Inacurrate modelling of the reality;
- Lack of solutions to react to new information and unexpected events;
- Lack of strategies to mitigate risks or overstock due to shifting timelines;
- The constantly shifting environment is a given. The way we react to it is not.

What solutions do we have for these drivers of waste?

Demand forecast and planning

Optimize the overage based on a prior risk assessment;

Scenario testing to plan for uncertainties;

Assessment of the robustness of our strategy to change;

Define realistic time safety margins instead of stock safety margins;

Define the safety margins with a global visibility on the end-to-end supply chain rather than locally.

Processes and communication channels

Optimize strategic decisions related to network and manufacturing strategies (outsourcing, scale-up, resource allocation, building new plants, etc...);

Assess the impact of decisions and processes on waste (e.g. stability plan, lot sizing, lot allocation constraints, etc...);

Have an end-to-end supply chain planning role, or a process to ensure alignment between the CMC and supply chain teams.

PRODUCTION APP

Q&A from the audience

Q1: How long does it take to implement an optimization solution?

R1: *The first optimized results for a clinical program can be obtained very quickly (1-2 weeks) through our team of expert consultants.*

A global implementation of tools and processes requires a comprehensive training and coaching program, and sometimes redefining roles and responsibilities. As any change management project, the whole process depends on the availability of the team and internal processes. N-SIDE provides tailor-made implementation services to help you realign your internal structure and get the most out of the tool as soon as possible.

Q2: Concretely, what can your tool bring to our production process?

R2: *Firsthand, the **Production App** provides **end-to-end visibility on the current and future supply chain**, allowing to plan in advance, run scenarios, assess risks and define an efficient production plan.*

*But the main added value of the Production App is its **optimization algorithm**, that will not only provide you with a feasible manufacturing strategy, as typical forecasting would, but the one **best solution that minimizes waste, costs and covers the demand**.*

*Depending on the scope, the optimization features can be extended to **strategic decisions**, like lot sizing, scale-up strategy, network design, vendor selection, stability planning, etc...*

*In the end, **the Production App alone reduces the waste at manufacturing by 20-40%**. When combined with the **Supply App, the numbers jump to an impressive 30-60%.***