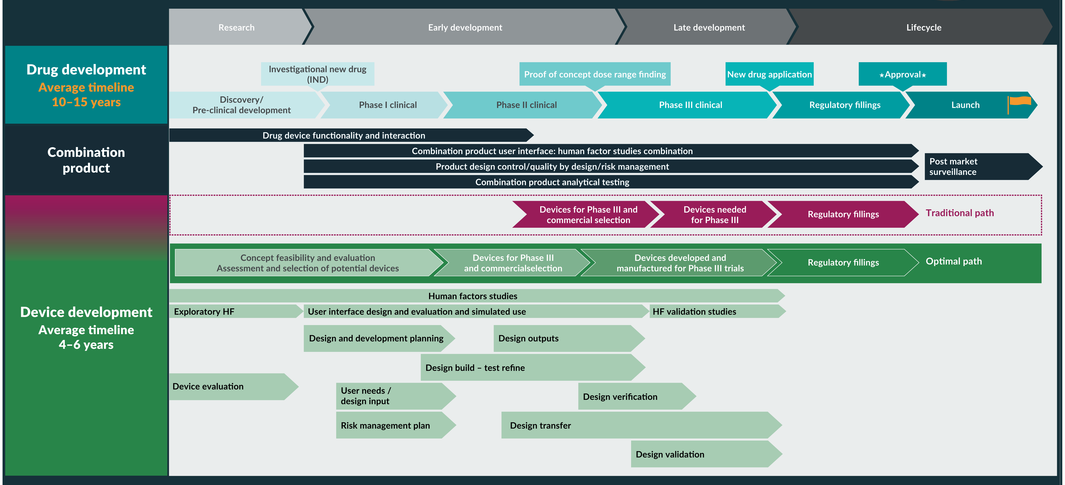
Drug device co-development challenges

Dr Soroosh Bagheriasl – Senior Account Manager

BioPhorum Drug Delivery's mission is to create an environment where the global drug delivery and combination products industry can collaborate and accelerate its rate of progress for the benefit of all

The foundation of Drug Delivery was developed by leaders and subject matter experts within Drug Delivery device development from existing BioPhorum member companies who came together to identify common problems and assess opportunities for collaboration across a range of topics including: EPRs/EDDOs, Human Factors, Regulatory, Risk Management, Sustainability and Biocompatibility



Let's bring the device team in early

- A well integrated Device team with full visibility of the drug pipeline
- Device development teams are not a subservient function but a standalone function with a seat at the table (exec leadership)
- Device team consulted early in the drug development process before a formulation exists to influence decisions and anticipate device-related challenges
- Embedding flexibility in the device design space and staying involved throughout the clinical development process
- The formulation team are aware of the limitations of the device portfolio and platforms
- Reduce risk by allowing more time for device development, a full appreciation of the device development timelines is essential considering the increasing complexity of devices

"Devices need to stay off the critical path for any program, but only early efforts will allow this"

"Device teams need to be brought in early, and accept the fact that you will be delayed to market if you don't"

"The device team should have a say over clinical needs perspective and user needs perspective before the drug goes into development"

"If the device team is not involved, then they have no say over clinical needs perspective and user needs perspective and by this point it is too late as the drug is already well into development"

"The drug is only as good as the device used to deliver it"

We are in phase 2 clinical... we need a device stat

- Device teams traditionally are brought in once the drug/therapeutic has experienced a successful phase 1
- Device teams are not consulted around the formulation, viscosity, volume and concentration of the drug which will impact the choice of final device
- The user profile, design inputs and commercial inputs dictated by the drug are not shared with the device team until phase 2
- Senior leaders don't always have device experience which necessitates the foresight to anticipate device-related challenges coming into phase 2
- No awareness of molecules that are going into phase 1 within the organization
- The formulation team are not aware of the limitations of current devices within the portfolio

"when you have a formulation in place you are limited with the devices, we can go forward with due to device limitations"

"Traditional mentality in drug development is they want to have the highest concentration and lowest volume"

"This is always a problem is that they come down for phase 2 and say, hey, we want to get this into a phase 2 trial next year and we say, that's not possible. You should have come to us sooner"

"The situation is improving but device development is still seen as a subservient effort"

"Device development is always on the critical path"

Those device people speak differently to us

Device design and development	Pharmaceutical development
Design Inputs	• Target Product Profile (TPP)
User Needs	• Quality Target Product Profile (QTPP)
Design Outputs	• Critical Quality Attributes (CQAs)
Essential Performance Requirements (EPRs)	• Specifications, Drawings, Labelling and Packaging
Device Master Record (DMR)	• Master Batch Record (MBR)
Design Reviews	• CMC Stage Appropriate Linking Drug Product CQAs • Critical Material Attributes (CMAs) • Drug Product Characterization and Stability • Critical Process Parameters (CPPs)
Design and Development plan	• Master Project Plan
Design Verification	• Phase 1/2 Clinical Evidence for Safety and Efficacy • Manufacturing Design Space • Process Inputs (CMA/CPP) and CQA Relationship • Suitability of Packaging System
Design Validation	• Phase 3 Final Formulation and Clinical
Delivery/Device System Functionality	• Defined Manufacturing Processes Controls
Human Factors	• Medication guidance and Errors,
Design Transfer	• Tech Transfer
DMR	• Drug Master File (DMF) /MBR
Design History File	• Product Dossier
Design Change Control	• Change Control, Continuous Improvement

biophorum.com/phorum/biophorum-drug-delivery/

© BioPhorum Operations Group Ltd

Questions to industry?

- Does your device team have representation at a senior level who can influence decision during drug development?
- At what stage of the drug development process is your devices team consulted?
- How well integrated is your device team do they have full visibility of the drug pipeline?
- Have you seen a change in your organization in recent times around how the devices team are integrated into the drug development?
- Is your devices team still seen as a subservient function
- Is your devices team given sufficient time for device development. Do they find themselves on the critical path?

Next steps

1. Gather more responses via survey - PLEASE SCAN QR
2. Build a consensus view around the current challenges in drug device development
3. Publish the results in a white paper with recommendations to industry on how to align drug-device development
4. Present the findings to Industry and to formulation teams across our network to build awareness of the challenges

Survey Link: https://forms.office.com/e/1GdJqRbrCb