A QUALITY PERSPECTIVE ON DRUG PRODUCT AND MEDICAL DEVICE DEVELOPMENT

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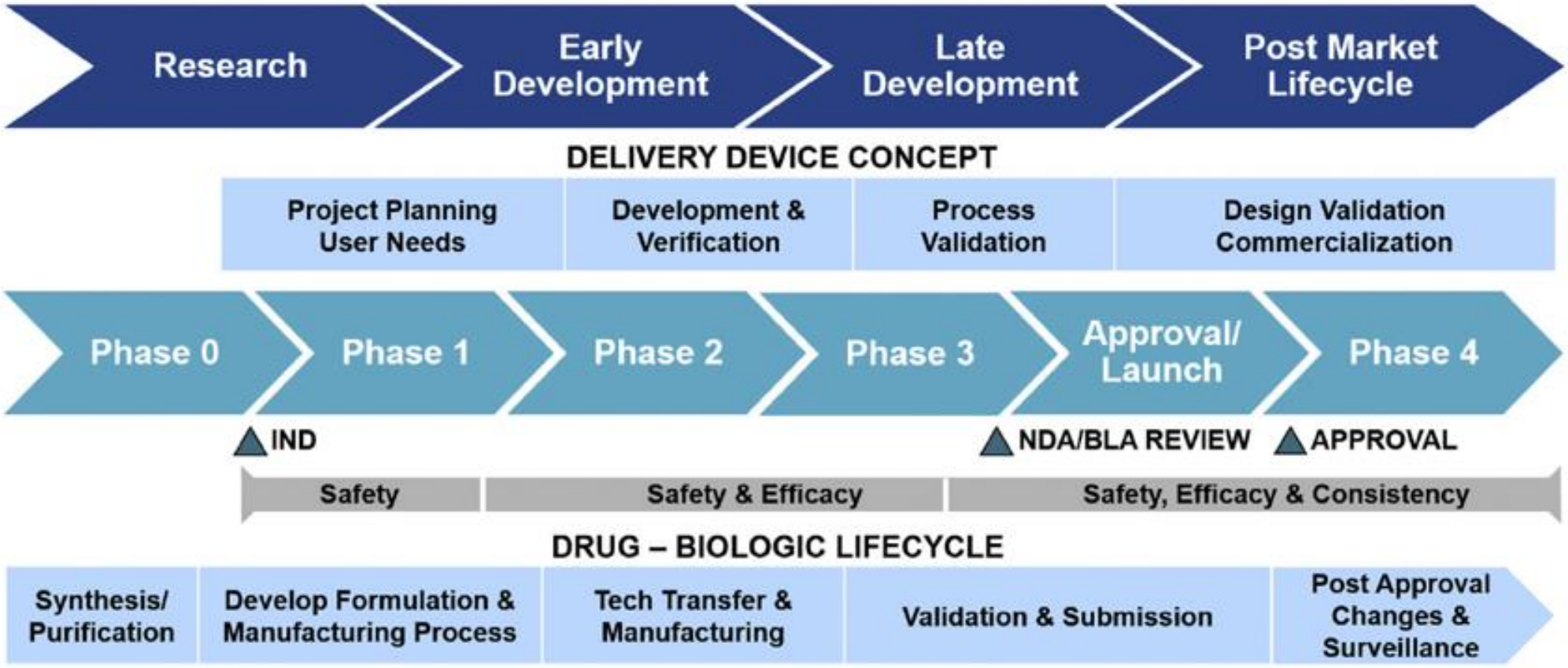
Drug and Device Development Phases

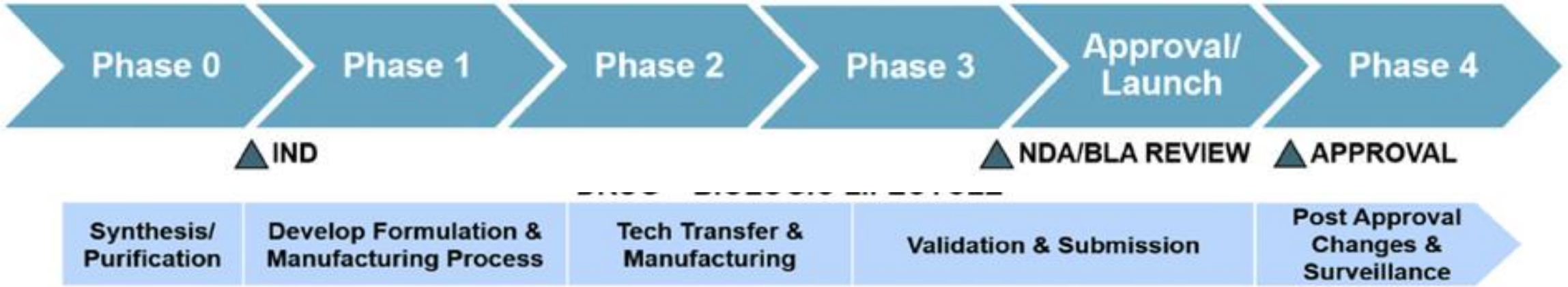


Source: https://drug-dev.com/combination-products-device-development-for-pharmaceutical-biologic-combination-products/

Drug and Device Development Phases

How Combination Product (CP) development fits in?

- CP development elements don't necessarily align with corresponding clinical phases
- Start of CP development can be dependent on many factors such as: supporting business case, device/CP targeted, user needs, business needs, clinical and regulatory strategy, etc.



Combination Product development
Easy/OTS DDSs (i.e. PFS, AI)

Combination Product development
Complex DDSs (i.e. Inhalers etc.)

Source: https://www.fda.gov/media/75273/download

Drug and Device Development Phases

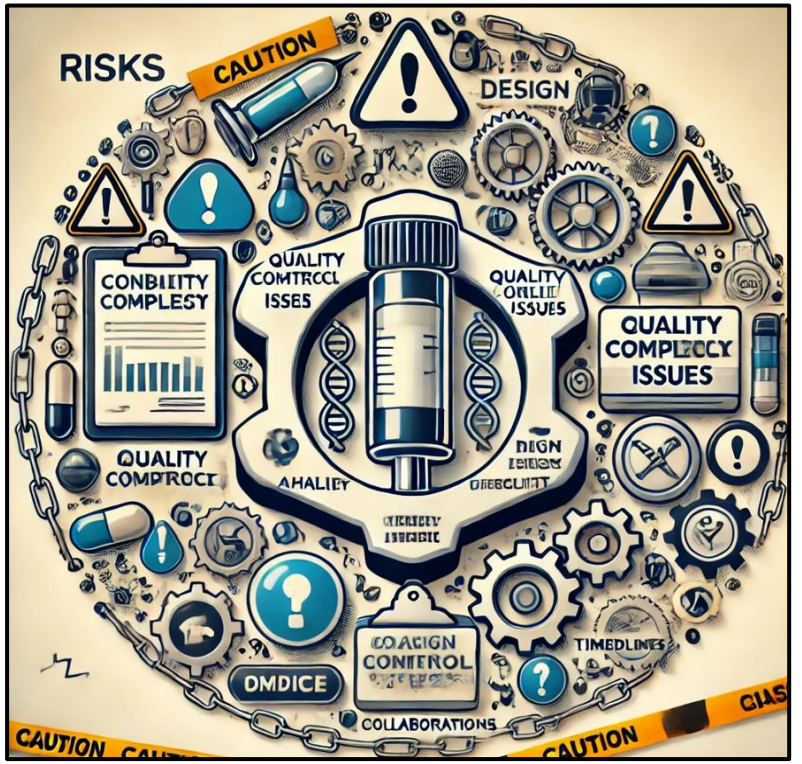
What are the challenges?

- Device/CP development adds time and complexity to any development plan. How often do we start device/CP development well on time!? When do CP development teams integrate into CMC teams?

- Device/Platform and CDMO selection, Test results from early drug characterization are used to inform integrated development plan. What about availability of DS/DP/device to support testing?

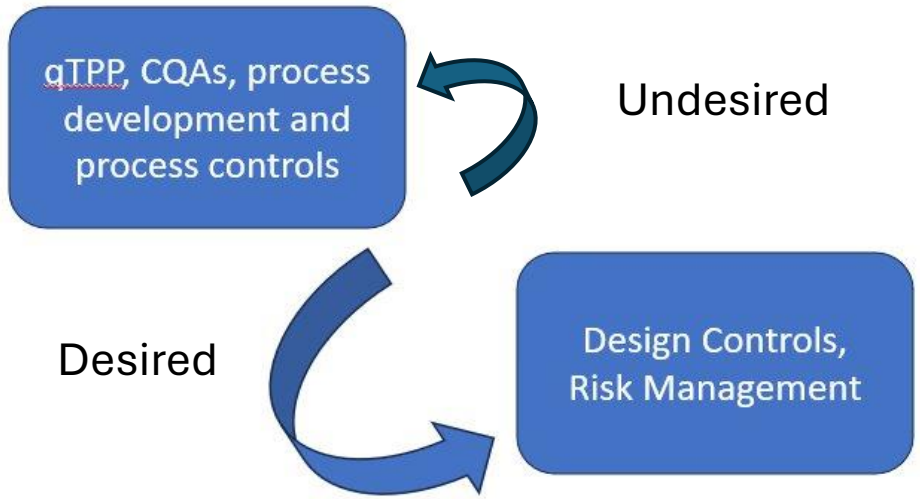
- Having multiple concurrent workstreams [e.g. vial v. Ph2 CP v. “Go-to-Market” device/CP] is a strain on resources.

- Business risks to consider: Cost + timing risk [does the commercial team want vial ASAP in the market or a device/CP for added value and pt experience, etc.]?



Drug and Device Development Phases

How does device/CP design control integrate into drug development stage gate?



	Drug Development	Device Development
Early Stage	Formulation development (Target Product Profile,qTPP)	Design Inputs (User needs, device requirements, use/hazard analysis)
	Process development (CQAs, CPP, stability)	Design Outputs (Specifications, prototypes, EPRs)
	Process Qualification (eng. Runs), charac. study	Design Verification & Validation
	Process Risk Assessment	Risk Management File (plan, D/U/P FMEA, report)
Late Stage	Tech Transfer (MBR)	Design Transfer (DMR)
	Process Validation	Process Validation
	Product lifecycle management	LCM, Post-market Surveillance

Table: High level comparison Drug vs Device Development

Drug and Device Development Phases – Risk Management

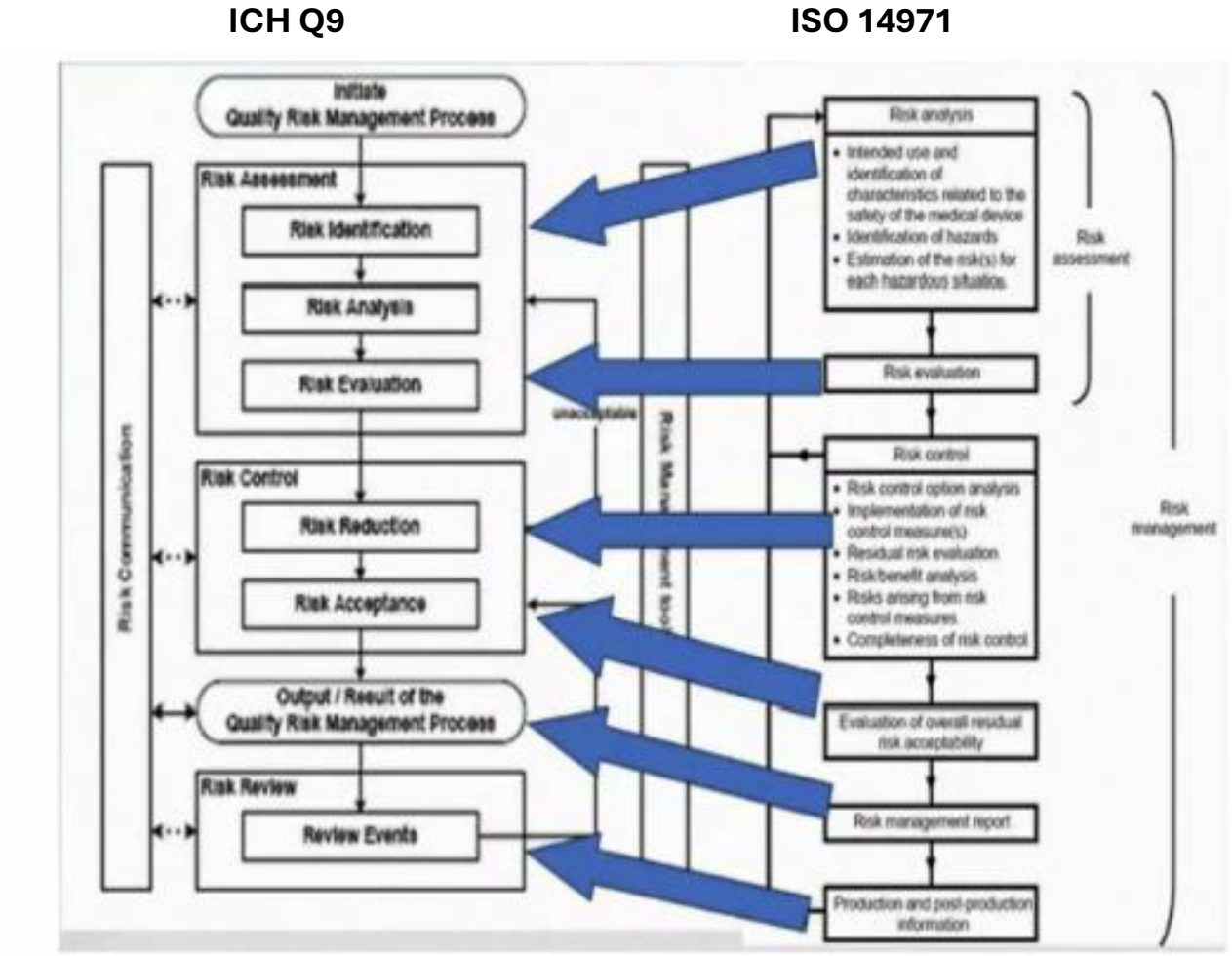
How does Risk Management methodology integrate into drug and device development stage gate?

- ICH Q9 is the guidance on Quality Risk Management For drug development and ISO 14971 is the Risk Management standard for device Development

- ISO 14971's approach is more prescriptive whereas, ICH Q9 champions flexibility

- Differences in definitions, RA techniques, Risk management file structure, benefit-risk analysis,

- Efforts ongoing to harmonize ICH Q9 and ISO 14971, Fostering consistency and efficiency across sectors

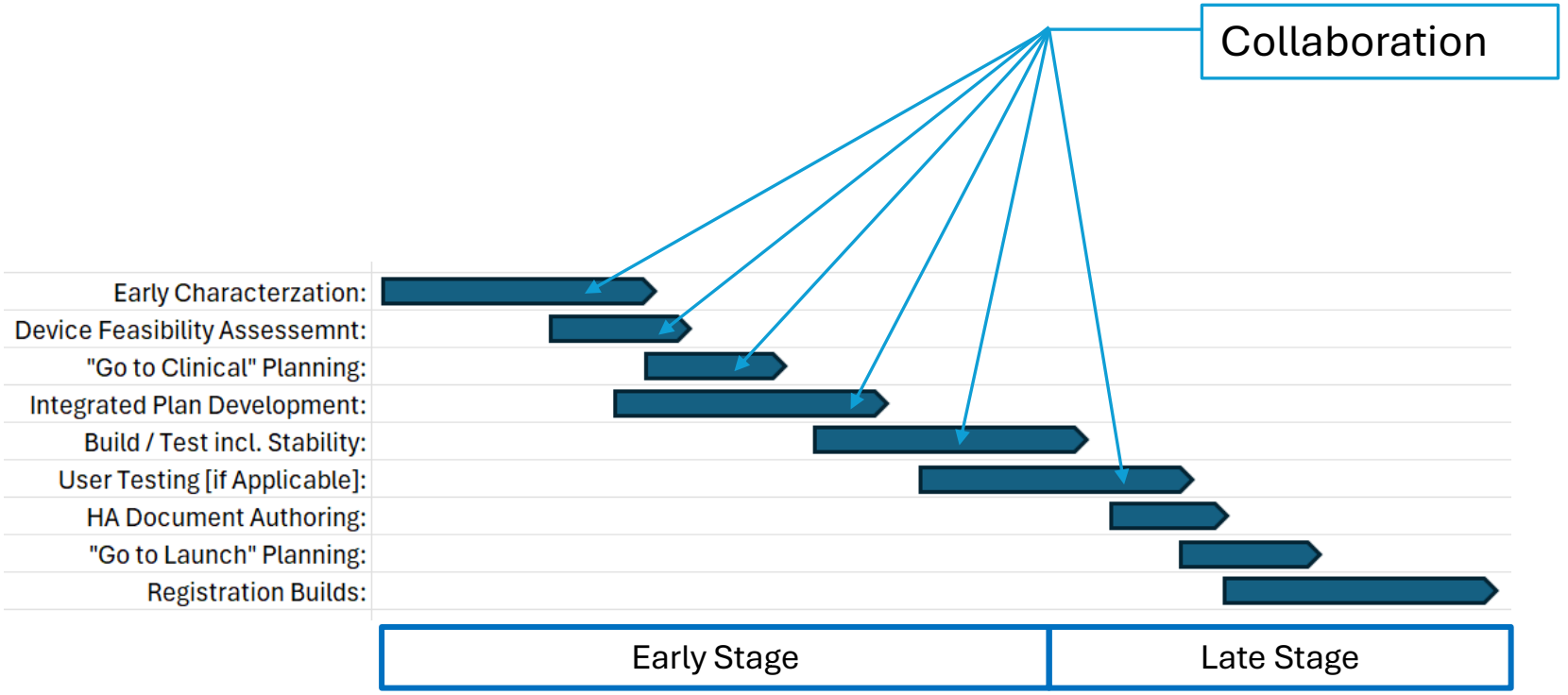


Source: ISO 14971 and ICHQ9 comparison www.mastercontrol.com

Drug and Device Development Phases - Collaboration

Identify collaboration areas for early device development

- Early program visibility and collaboration for and during characterization is critical
- Integrated team typical make-up: DS, DP, Clinical, Device, RA, Quality, MFG
- Early collaboration with Clinical and Regulatory teams to support development and submission strategy



Q & A

thank you
danke
謝謝
ngiyabonga
teşekkür ederim
gracias
merci
obrigado
рахмат
Баярлалаа
спасибо
faafetai lava
mersi
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