COMBINATION PRODUCTS SUMMIT

FT. WORTH, TX • NOVEMBER 28–30, 2023

Platform Drug-Delivery Devices:

Regulatory and Technical Considerations

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AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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Food and Drug Omnibus Reform Act (FDORA) defines a Platform Designation Program.

WHAT?

Requires FDA to create a designation program for "platform technologies*."

Platform technologies are technologies that have the potential to be incorporated in or used by more than one drug or biological product and are reasonably likely to make the drug development or manufacturing process and the review process more efficient.

SO THAT?

FDA may expedite the development and review of any subsequent applications.

Sponsor may reference or rely upon data and information from a previous application that uses the same platform technology.

*Refer to Section 2503 of FDORA for further information of the platform designation program.

How does the drug-delivery device platform apply in concept and in practice for the pharmaceutical industry?

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DEVELOPMENT OF PLATFORM DEVICES IN CONCEPT

Platform Devices are developed with pipeline in mind to accelerate clinical development and commercialization of multiple molecules

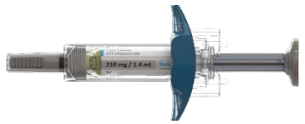

Molecule A


Molecule B


Molecule C


Molecule D


Multiple molecules



Platform PFS-NSD

Development of a platform PFS-NSD to deliver multiple molecules

DATA SUPPORTING EACH MOLECULE

Molecule-agnostic data

Molecule-dependent data

The "why" behind device platform?

Ability to leverage existing knowledge and previously collected data, if justified.

01

Streamline and accelerate clinical development and commercialization of combination products to serve patients and users.

02

Reflects the least burdensome approach in the lifecycle management of combination products.

03

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DEVELOPMENT OF PLATFORM DEVICES IN PRACTICES

Experience from AbbVie and Merck

The AbbVie Journey on "Device Platform" Approach

- It started within the Systems Engineering team soon after it was created.
- **Quickly saw benefits:** less time, more efficient, lower costs, lower risks…
- **Elements of a platform:** Design (Inputs, Outputs, Verification, Validation, Transfer, Risk), DHF, and Manufacturing
- Robust Platform assessment during feasibility and development
- "Device Platform" approach is currently a component of a larger initiative

Key words from Chin

Molecule-Agnostic | Molecule-Specific

Key words from Kent

Systems Engineering | Elements of a Platform | Robust Platform Assessment

In Jiaying's Presentation

Illustrate how Merck identifies the "Molecule-Agnostic" vs "Molecule-Specific" "Elements of a Platform" systematically and conduct "Robust Platform Assessment"

Provide one example of testing "Platform Approach" with real products and lesson learned

The First Step to Explore the "Device Platform" Approach

Work with device vendors and functions involved in combination product development to answer the following questions:

What are the activities between "device platform" and "clinical" or "commercial" product

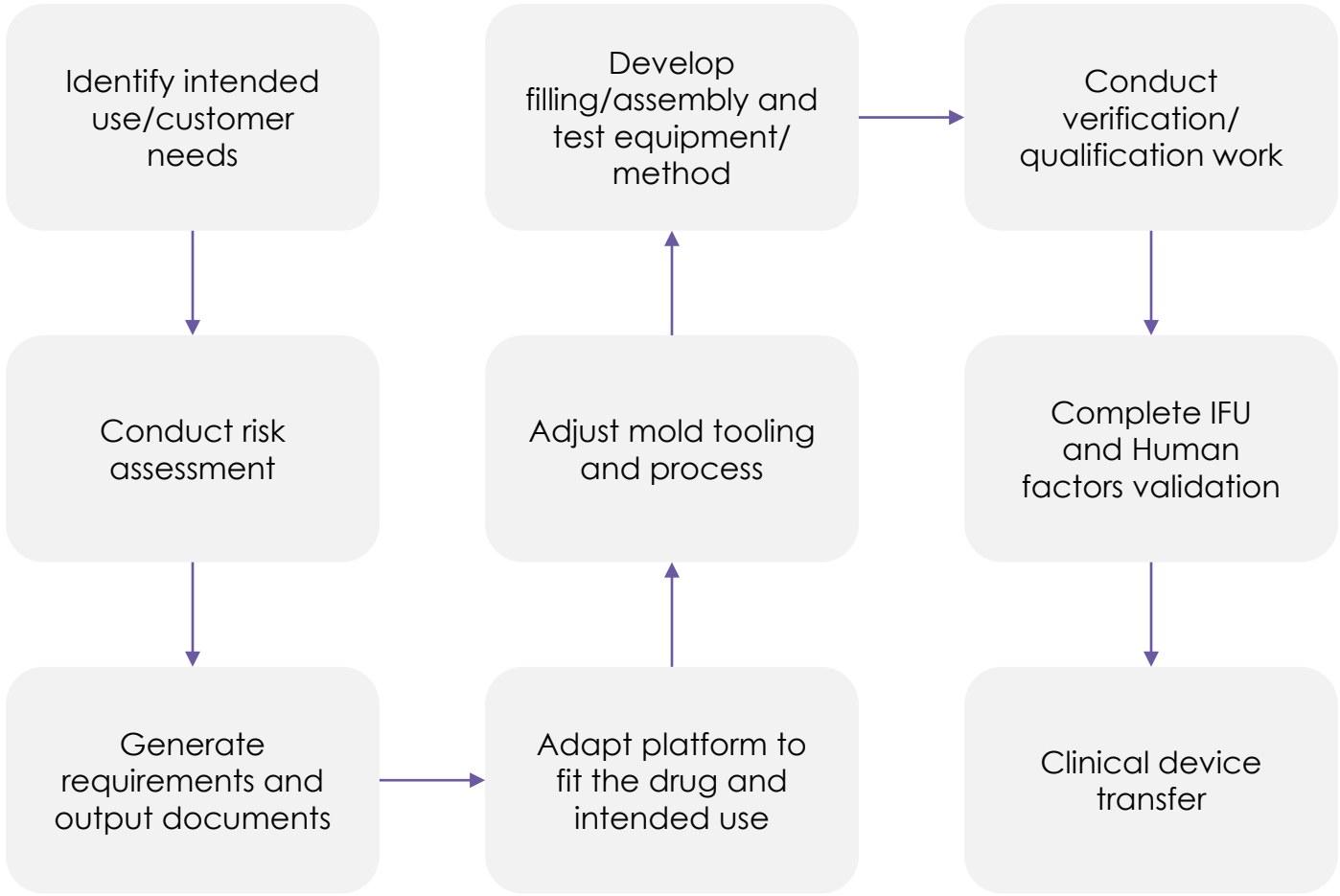
What type of work can be:

- Standardized and re-used
- Bridged and leveraged
- Start from scratch

Why

Auto injector Example

Activities between "Platform" and Clinical Entry



Auto injector Example

Deep Dive into Each Box with Questions

What type of work can be

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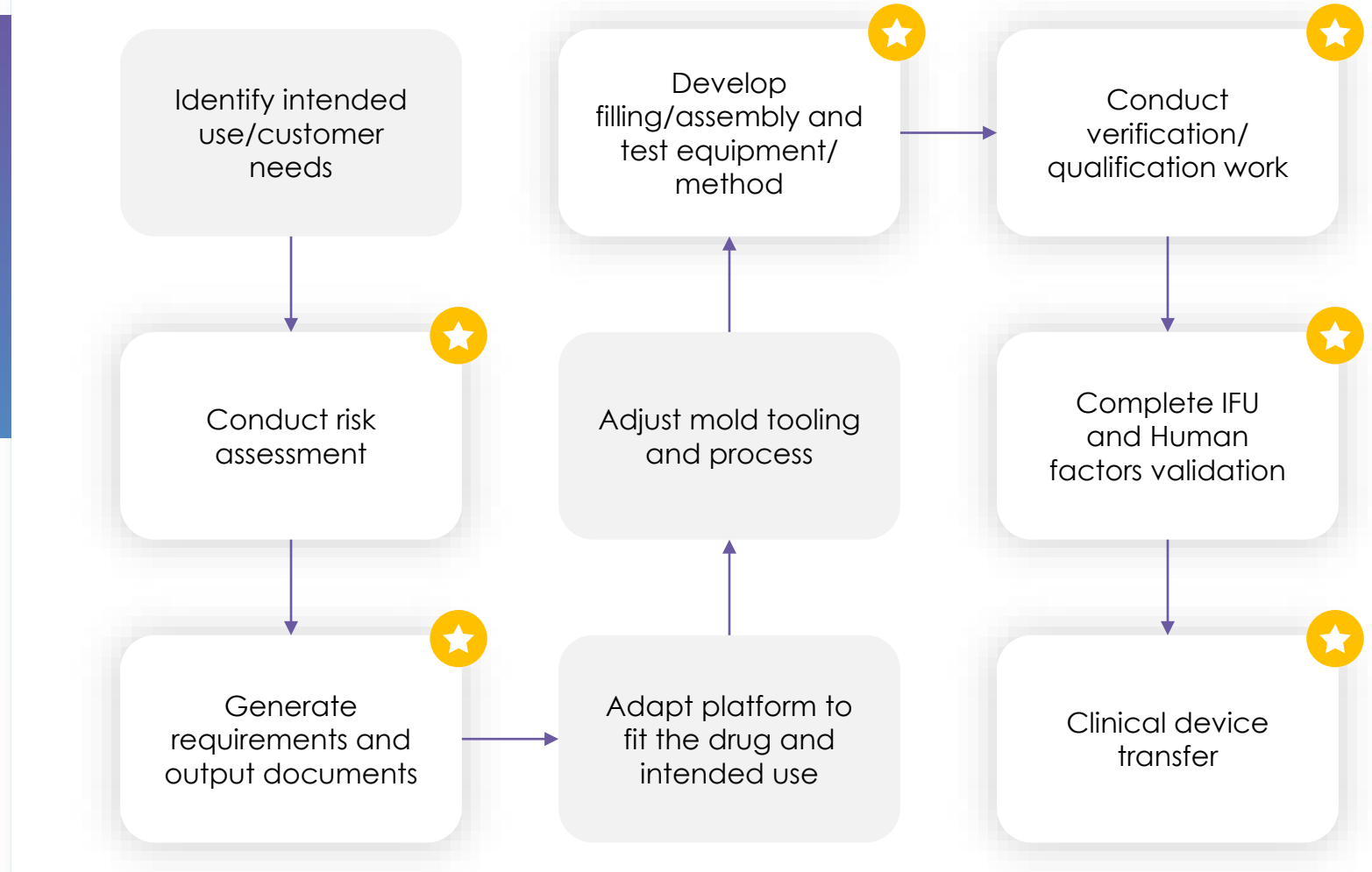
Why



Elements of a Platform	"Molecule-Agnostic" Examples	"Molecule-Specific" Examples
Design Inputs	Functions – what the device needs to do	Inputs driven by specific users and use environment
Device Characterization	Majority of characterization methods	Material interaction with molecule
Design Requirements and EPR	Needle extension, Shipping requirements	Viscosity, volume, stability related requirements
Design Verification	Most Design verification methods and some tests e.g. cap removal force	Dose Accuracy; injection time
Biocompatibility Strategy	Can be reused if the same contact materials,	N/A
Assembly/Filling Equipment	Operation steps and some quality checks	Re-qualify equipment for different molecules
Device Risk Management	Hazards, failure modes, root causes, some risk control measures	Harm, Severity, P2
Human Factors	Overall flow of instructions for use	User specific tests
Design Transfer	The category of DHF	Site specific information

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"IT DEPENDS"

Primary Packaging (container closure), color change, spring change, assembly/packing process

Coupling molecules with the device platform may necessitate additional platform development work

	Product A	Product B	Difference
Syringe Barrel	1.5mL XX Baked from the same vendor	1.5mL XX Sprayed from the same vendor	Different components with different siliconization process due to particle consideration
Stopper	Stopper A	Stopper A	No difference
Plunger Rod	Plunger Rod from vendor A	Plunger Rod from vendor A Plunger Rod from vendor B	Product B requires a second plunger rod as a backup due to volume concern
Finger Flange	None	Yes	Product B requires finger flange for its pediatric indication
Filling Site	Internal site	External site	Different sites with different capabilities
Packaging	Thermoformed tray	Paperboard tray	Different equipment and different shipping tests
CCI Testing	QPLT	Dye Ingress	Different CCI methods
Design Verification	Internal site	External site	Probably equivalent test methods but different acceptance criteria

Lesson Learned

Platform does not mean "one size fit all", "re-useable" or "interchangeable". Most platform elements have both molecule specific and molecule agnostic parts.

The key word is "it depends" – there are many factors that can impact the platform strategy

The molecule attributes might be the biggest factor

Try to keep these 5 areas as same as possible or like to like/interchangeable

- Device components design or selection (e.g. outshape)
- Materials selection (including color and spring)
- Device component mafucaturing process
- Drug/biologics filling process
- Combination product assembly and packaging process

These impact the % of molecule specific and molecule agnostic work and need to be evaluated case by case for each project

My suggestions

- Plan early
- Do through device characterization work with molecule as early as possible
- Keep asking your pharmaceutics colleagues questions early and collaborate. Don't assume something is molecule agnostic
- Analyze the 5 areas and compare your product under development with your platform device in these 5 areas
- Start to map your supply chain as early as possible
- Be open to change (don't be afraid)
- Need to justify any data that will be re-used
- Don't forget risk assessment