POSTER 73

Developing Framework for Flexible and Robust Real-Time Release Testing

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Right First-Time Manufacturing of Pharmaceuticals (RiFTMaP)

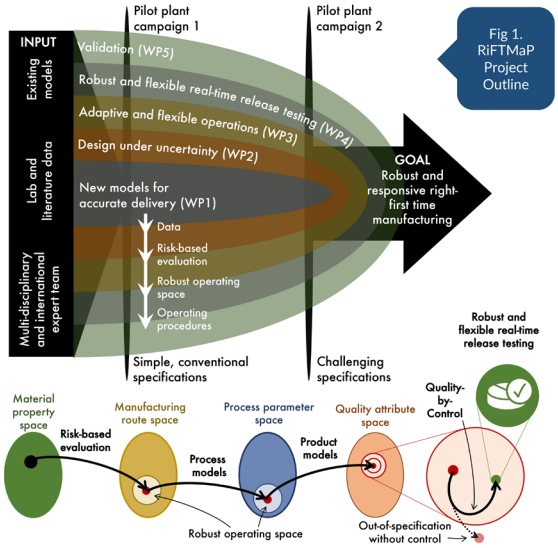

Fig 1. RiFTMaP Project Outline

Increased opportunity to implement RTRT in manufacturing lines due to advances in process analytical technology and digital manufacturing. [1]

- A three-year, £1.5m EPSRC collaboration between the **University of Sheffield**, **University College London**, **University of Strathclyde** and **Purdue University**.
- Developing **right-first-time** smart manufacturing systems incorporating **Industry 4.0** concepts within a systematic framework for **smart continuous manufacturing.**

*Development of a framework and computational tools for **optimal design** of pharmaceutical processes with **real-time process management system** and a **flexible real-time release framework**, all **verified** at pilot scale.*

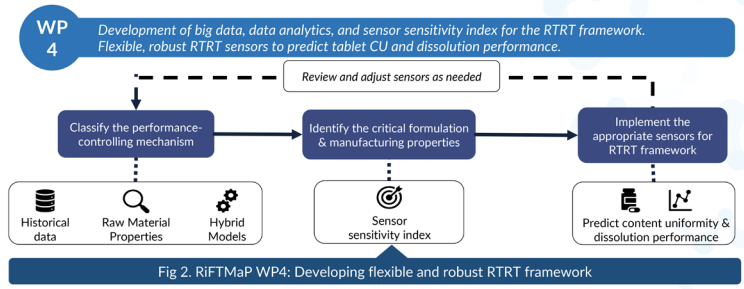

Fig 2. RiFTMaP WP4: Developing flexible and robust RTRT framework

Performance-Controlling Mechanisms of Tablets

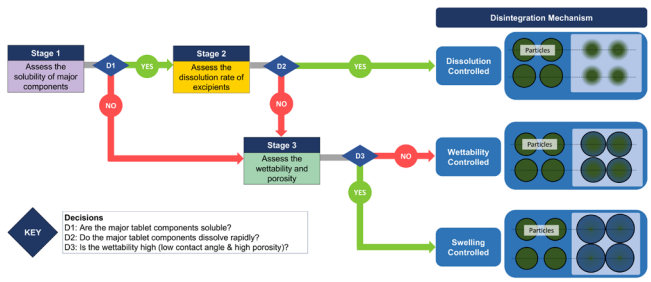

Fig 3. Workflow for the classification of the performance-controlling mechanisms of immediate-release tablets. [2]

- *Mechanisms determined by **raw material properties** and the **process conditions***
- *Allows the identification of **critical formulation and manufacturing parameters** which influence the **performance** of a specific formulation*
- *Use this knowledge to **identify** the appropriate **sensors** for RTRT*

Identifying the Critical Formulation & Manufacturing Properties

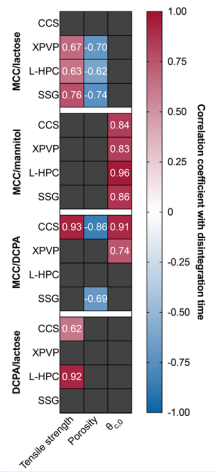

Fig 4. Pearson coefficients for the change in tablet properties with disintegration time. [3]

Wettability controlled
Disintegration time sensitive to changes in tensile strength & porosity

Dissolution controlled
Disintegration time sensitive to changes in contact angle (wettability)

Swelling controlled
Disintegration time is not strongly affected by tensile strength, porosity or contact angle.

Predicting Performance

Raw Material Properties

- *Surface energy*
- *Particle size & shape*
- *Moisture sorption*
- *Solubility & intrinsic dissolution rate*
- *True density & intra-particle porosity*
- *Surface area*

Performance of Tablets

Compare and model dissolution profiles for a range of different API, formulations & manufacturing settings

Development of data driven models to predict product performance

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Scan for more on this project

References

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2. Maclean, N. et al. (2021) Exploring the performance-controlling tablet disintegration mechanisms for direct compression formulations. Int J Pharm, 599, 120221.
3. Maclean, N. et al. (2022) Investigating the role of excipients on the physical stability of directly compressed tablets. Int J Pharm: X, 4, 100106.

MCC – microcrystalline cellulose; DCPA – dibasic calcium phosphate anhydrous; CCS – croscarmellose sodium; XPVP – crospovidone; L-HPC – low-substituted hydroxypropyl cellulose; SSG – sodium starch glycolate; $\theta_{c,0}$ – initial contact angle.

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