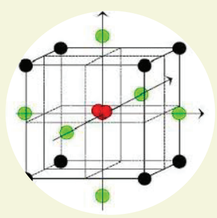
Joint BWP/QWP/GMDP IWG – Industry

European Workshop on

LIFECYCLE MANAGEMENT

Problem Statement

Regulators want visibility to changes to "established conditions" post approval



Industry wants flexibility to manage post approval improvements to minimize supply chain complexities

Data rich submissions have seemingly translated to more post approval submissions with higher reporting categories

Challenges in Post Approval

Currently, established conditions are defined*

If established conditions are based on criticality, only critical parameters should be identified in control strategy

During application review, additional non-CPPs often get introduced per HA request

Non-CPPs are managed in post approval the same as CPPs

*Elements of the control strategy that ensure process performance and quality of approved product

Example of Filing Classifications

	Traditional Filing	QbD/ Risk Based Filing
Change Paddle Feeder Speed During Tablet Compression	• No change to physico-chemical properties • No impact to product quality • No change to IPCs or specifications	
Same Change		Introduction or extension of an approved design space for finished product
Type Ia Variation	Data in submission • Dissolution profile • Batch analysis data • Commitment to monitor on stability • Updated CTD sections (P33 and P54)	
Type II Variation		Data in submission • Results from Risk Assessment, including multivariate analysis • Tabulated summary results of new DoEs executed to establish new DSLs • Updated CTD sections (P23, P33, P34, P54)

Solutions

Only list CPPs in control strategy

Protocol

Use a PACMP to manage proposed changes to established conditions in approved application

Components of a PACMP

- One protocol for review and approval
- Content of protocol includes experimental plan and acceptance criteria as it relates to parameter criticality
- Ability to execute the approved PACMP multiple times
- Two tier approach for reporting categories