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Advancing Generic Drug Development (AGDD) – Webinar
Developing Pediatric Formulation (Regulatory Considerations)



Developing Pediatric Formulation

Overview

- **Definition of Pediatric Population**
- **Quality Target Product Profile (QTPP)**
- **Product Quality Attributes/Target Product Profile**
- **Meeting End User Expectations**
- **Conclusion**

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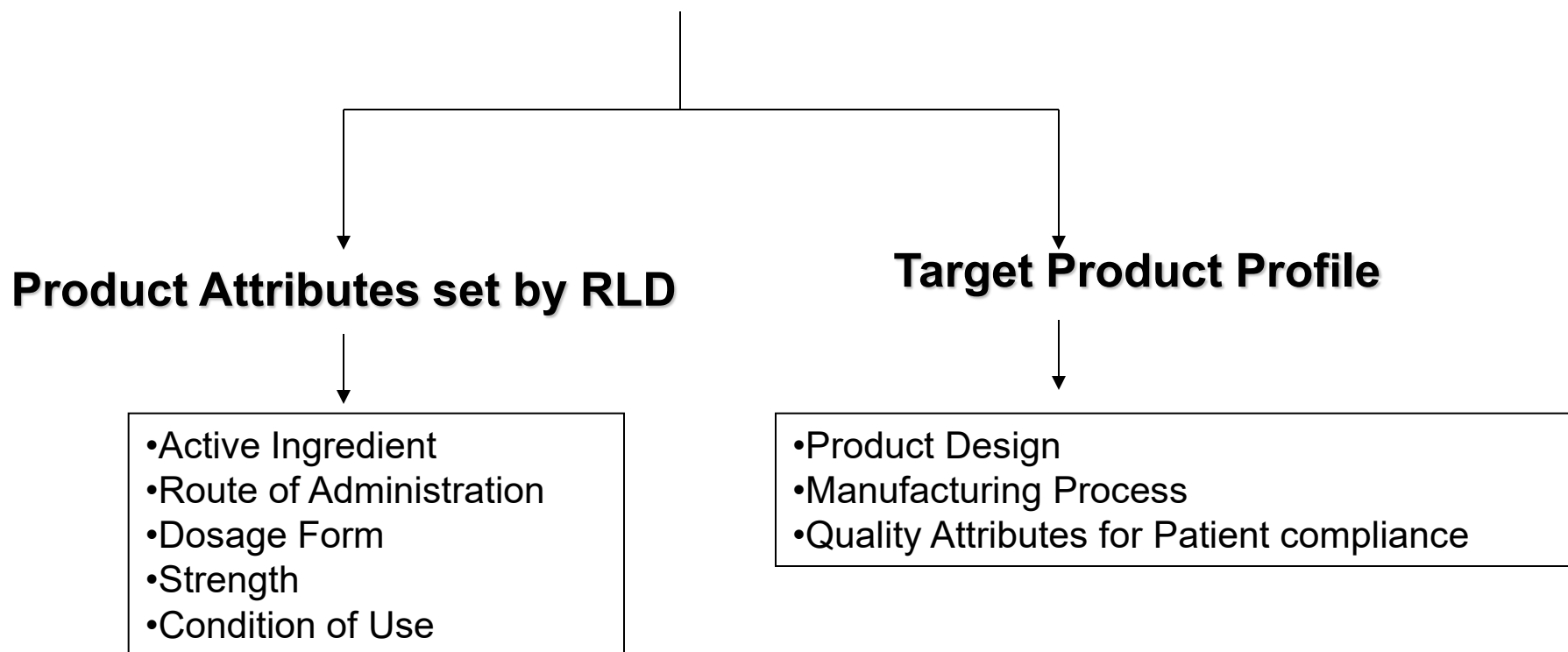
Definition of Pediatric Population

- **Federal Food, Drug, and Cosmetic Act (FD&C Act) defines pediatric patients as persons aged 21 or younger at the time of their diagnosis or treatment. Pediatric subpopulations are further categorized as follows:**
- **Neonates - from birth through the first 28 days of life.**
- **Infants - 29 days to less than 2 years.**

Dose and Administration

- **Intended Population**
- **Route of Administration – Product formulation impact on pediatric population compliance based on how the product is administered**

Quality Target Product Profile (QTPP)



Developing Pediatric Formulation Target Product Profile

- ICH Q8(R1) definition:
 - “A *target product profile* is a prospective and dynamic summary of the quality characteristics of a drug product that ideally will be achieved to ensure that the desired quality, and hence the safety and efficacy, of a drug product is realized. The target product profile forms the basis of design for the development of the product.”

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Target Product Profile

- Product profile for pediatric population may differ from the other population within the same RLD/NDA.**
 - Drug Product physical aspect may differ for pediatric population**
 - Product administration**
 - Critical for pediatric population compliance based on how the product is administered**

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Target Product Profile

Product Design

- **Drug substance properties (physical and chemical)**
- **Excipient selection to meet palatability expectation**
 - **Provide intended function of excipient**
- **Impact of excipient on manufacturability and meeting the dose administration goal**
- **Formulation and Process selection to meet product stability and enhance palatability**

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Product Quality Attributes

Product Design

- **Capture key Product Design and prior knowledge in product development report**
 - Describe product design and explain its strategic impact in meeting clinical outcome
 - Identify risk to quality and/or performance by variation in supply chain and/or process
- **Discuss elements essential for patient compliance**
 - Design strategy to address palatability and taste in selection of final formulation in product development.
- **Product design aspect to cover in-depth**
 - Applicability of guidances in addressing pediatric population.
 - Impact of formulation on product use recommendation
 - Palatability/Taste
 - Swallowability – SODF
 - Risk Assessment and Mitigation

Product Quality Attribute

Palatability:

- **Palatability is the hedonic, subjective measure of how pleasant or acceptable a food, beverage, or drug is to consume, encompassing taste, aroma, texture, and appearance.**

Taste:

- **Patient non-compliance due to poor taste is a major barrier to treatment, affecting up to 91% of patients with acute illness and 84% with chronic conditions.**
 - **By some account 75% of API are reported to be bitter.**

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Container/Closure

Container Closure System

- **May have suitable device for dispensing the drug product.**
- **Discuss suitability of device on the product stability and performance over shelf life**
- **Provide studies to demonstrate that the C/C system will protect the product during storage, shipping and use**

Risk Assessment and Mitigation

- **Provide risk analysis of C/C selection and basis of C/C selection**
- **Identify risk to quality and/or product elegance**
- **Provide appropriate mitigation plan**

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Conclusion

- **Tailor the patient need and compliance based on dosage form .**
- **Pharmaceutical Science and Development should be well presented**
- **Desired Product Performance Attributes should be well articulated**
- **Performance Attributes should be built in the development process rather than determine by end-product testing**



Acknowledgement

OPQ & OGD Management