Primary Packaging Design Innovation (PPDI) to improve supply chain efficiency

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PROLOGUE

The demographics & vaccination schedule of a country dictates cold chain space requirement. In most scenarios, especially in developing countries, availability of cold chain space is limited and struggles with new vaccine introductions impacting access. We had an experience with a country where decision of new vaccine introduction was held back due to constraints of cold chain space availability. Expansion of cold chain space is resource intensive activity. The proposed concept on primary packaging design innovation is an attempt to improve supply efficiency by reducing cold chain space need during storage, shipment and distribution.

PRIMARY PACKAGING

Vaccine Presentation and Packaging Advisory Group (VPPAG)[3] recommended generic preferred product profile for vaccines. Where technically possible manufacturers are encouraged to reduce height of the "2R" vial from 3.5cm to 3.1cm or less for cold chain volume reduction. Currently GSK is using the 2R standards with vial height of 3.1cm for its single dose to four dose vials.

Reducing height of vial conflicts with labelling demands. At one end we have expectation to reduce the vial height which naturally impacts labelling space. On other hand we have minimum requirements for labelling (generic name, brand name, manufacturer/importer/marketer, manufacturing & expiry date, batch/lot number, dose volume, number of doses in the container, storage conditions, method of administration, product retail price, medical practitioner prescription warnings, etc.) and minimum viewing area. Immunization Program Stakeholder in recent informal communication to manufacturer suggested to include 'date & time box' on label. The intent to have time and date box on label is to help vaccination service providers to write date and time of opening the vial so as to follow vaccine usage guidelines of using within specified time and period. It can be used as monitoring tool as well. However, labelling space constraints prevents such useful additions to label beyond minimum required parameters.

DESIGN INNOVATION

We could not find any standard comprehensive guidelines on design change validation. Here we have made an attempt to structure some of the essential steps that will be required for validating any design change. From innovation to implementation journey is long and resource intensive. Factoring failure of innovation in real world, validation exercise needs to be done sequentially in three stages Viz. Pre-Manufacturing; Manufacturing and Post Manufacturing. Validation Master Plan will essentially be part of project document. Learning at each steps will help in building validation guidance for future innovations.

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[1] GlaxoSmithKline Pharmaceuticals Limited, India
[2] GlaxoSmithKline Biologicals, Wavre, Belgium
[3] Generic Preferred Product Profile for Vaccines, Version 2.1, March 2015, VPPAG recommendations

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PRE-MANUFACTURING STAGE

Any change in Primary Packaging Design needs to be evaluated the way existing vials are assessed like Certificate of Analysis (COA) by vial supplier, Visual monitoring, thermic resistance, hydrolytic resistance (Alkalinity), arsenic test, center of gravity, silicon homogeneity test, AQL complementary test, compression test, non-viable particle count, bioburden test, bacterial Endotoxin test, etc.

MANUFACTURING STAGE

The design change may require no change / minor (only adjustment in existing line) / major (requiring part replacements) changes in manufacturing line during various process of washing, sterilization, filling, sealing, capping, labelling and packaging. Post changes in the manufacturing line will require Technical Risk Assessment (TRA) to assess Quality / Process Parameters like needs to be done like Glass Delamination, visual inspection of filled vials, antigen compatibility study, thermos-stability, impact on speed of filling, pasting labels and packaging.

POST-MANUFACTURING STAGE

Once the manufacturing feasibility is successful it will require informing regulatory authorities[4] of the design change followed by post manufacturing validation / operational studies to assess real life improvement in supply chain efficiency from point of storage, shipment, distribution, usage at field level and disposal. The learnings later need to be documented and disseminated.

IMPACT on SUPPLY CHAIN EFFICIENCY

Supply chain efficiency will be measured by quantitative (direct and indirect) and qualitative assessment during post manufacturing stage. We propose direct quantification of cold chain space and weight reduction at various levels, shipment cost reduction and indirect quantification by estimating electricity savings and environmental advantages. Qualitative assessment will be based on feedback from various stakeholders involved in journey of vaccine vial from manufacturing plant till last mile vaccinator. An attempt will be made to build a mathematical model using project data as input parameters for overall predictions if all vaccines of public health importance switches to use proposed primary packaging design.

EPILOGUE

GSK is ready with concept for Primary Packaging Design Innovation with potential of minimum ten percent reduction in cold chain space requirement during storage, shipment, distribution; increase in labelling space and reduction in shipment cost. Preliminary feasibility assessment at Manufacturing line seems promising although with challenges. We are in process of developing business case for the proposed project. Validation exercise is an important component of the project. We are looking for guidance / partners / resources to develop and implement Validation Master Plan (VMP) for Post Manufacturing stage.

[4] Guidance for Industry, Changes to an Approved Application: Biological Products, USFDA July 1997

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Please send your suggestions / guidance for the proposed project along with your interest for partnership to sanjay.t.gandhi@gsk.com with subject line starting with PPDI.

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