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Study of Life Cycle Strategies in the Pharmaceutical Field

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Abstract: *Life Cycle Management (LCM) in the pharmaceutical industry refers to the strategic approach of maximizing the value and lifespan of a drug product from its initial development through to its commercialization and beyond. This involves a comprehensive process of planning, monitoring, and adjusting various aspects of the drug's life cycle to ensure continued relevance, efficacy, and competitiveness in the market. LCM encompasses activities such as formulation optimization, patent management, regulatory compliance, market expansion, and lifecycle extension through the introduction of new indications or formulations. By proactively managing all stages of a drug's life cycle, pharmaceutical companies can enhance patient access, maintain market share, and sustain profitability while meeting evolving healthcare needs and regulatory requirements.*

Keywords: Lifecycle Planning, Risk Management, Supply Chain Management

I. INTRODUCTION

Life Cycle Management (LCM) in the pharmaceutical industry is a strategic approach aimed at maximizing the value of a drug product throughout its entire life cycle. From initial research and development through to commercialization, patent expiration, and beyond, LCM encompasses a range of activities and strategies designed to optimize the product's performance, maintain its relevance in the market, and ultimately extend its profitability. In an industry characterized by rigorous regulatory requirements, intense competition, and rapidly evolving technologies, effective life cycle management is essential for pharmaceutical companies to adapt to changing market dynamics, sustain product differentiation, and meet the diverse needs of patients and healthcare providers. This multifaceted process involves continuous assessment, innovation, and strategic decision-making to ensure the sustained success of pharmaceutical products amidst dynamic market conditions and evolving healthcare landscapes.

- Manufacturing process development and scale-up
- Development of analytical methods
- Transfer of technical knowledge Transfer of new products takes place during the development process of And continues into production.
- Transfer within a manufacturing facility or between a manufacturing facility and a testing facility for Commercial products
- Manufactured in the commercial sector

PRODUCT LIFECYCLE MANAGEMENT (PLCM) DOCUMENT

• A detailed approach for managing the product lifetime is outlined in the PLCM paper. This covers all CMC post-approval requirements, EC, PACMP (where applicable), and reporting categories for EC modifications. Its goals are to support marketing authorization holders' future lifecycle management strategies and to make regulatory inspection and assessment easier. The documentation for PLCM should be updated as required throughout the life cycle of the product. The PLCM document reports Categories for EC modifications and serves as the EC's MAA primary repository. This comprises the key components listed below as well as Appendix IF's References to pertinent material elsewhere in the MAA. The template for the PLCM document is significant when MAH suggests an EC in Chapter 3 that adheres to the risk-based Approach. Below is a summary of the PLCM document's contents.

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• Post-approval CMC Requirements: At the time of approval, regulators and holders of marketing approvals agreed on certain CMC development activities (eg, monitoring of specified Processes, extra testing). The PLCM documentation need to provide a list of the actions taken. A detailed strategy for product lifecycle management is outlined in the PLCM documentation. This covers all CMC post-approval requirements, PACMP (if applicable), EC, and reporting categories for EC modifications. Its goals are to support marketing authorization holders' future lifecycle management strategies and to make regulatory inspection and assessment easier. The documentation for PLCM should be updated as required throughout the life cycle of the product.

APPROACHES FOR CMC POST-APPROVAL CHANGES:

Identifying ECs with relevant reporting categories is one way to simplify the process of making Specific CMC modifications for products without market clearance, in addition to the other methods outlined in this advice. needs a strategy. This chapter discusses the data requirements for CMC changes (e.g., stability) and presents a structured strategy for frequent CMC changes. Annex II provides an example of a technique for changing analytical procedures, which exemplifies the systematic approach to frequent CMC modifications. It would be possible to create and implement similar organized approaches for other frequent CMC changes, such size and packaging. These methods can be used if the following circumstances are met: • The company's PQS change management procedure is efficient, compliant, and includes a suitable risk management system, as outlined in Chapter 6; • Annex II provides a structured method that outlines the steps to be taken, including, where applicable, the data to be generated and the criteria to be satisfied. As part of the organized approach, compliance with the requirements of applicable international standards and/or regulatory guidelines may be stated. The modification may be made with immediate or other post-implementation notice, as applicable, to the relevant regulatory authorities provided the methodology is followed and all requirements are satisfied. Certain particular adjustments may need prior permission as defined in regional advice; the flexibility offered in Annex II may not be accessible in all regions and circumstances.

STABILITY DATA TO SUPPORT THE CMC CHANGES

The information needed to provide regulators with a post-approval amendment is governed by municipal laws and ordinances. Confirmation Stability Research Strategy may be developed using an extra scientific and risk-based method, which is provided by this guideline. This backs post-approved modifications as well as quicker change submission, approval, and execution. Make it feasible. PACMP may include such a technique (see Appendix ID and IE). Unlike the official stability test suggested by the ICH Q1A (R2), this one tries to determine appropriate storage conditions and a useful shelf life for novel medications that are not yet on the market.Goals of Substance/Drug, Stability Testing If Necessary supporting CMC modifications after IS approval in order to validate previously authorized shelf life and storage circumstances. Based on the information and experience of drugs and APIs gained since approval, the scope and design of such stability studies are determined. A well-reasoned design strategy for the study might include the following elements: An effective instrument for evaluating the effects of suggested modifications. This comprises: • Research on drugs, drug acceleration, and/or drug exposure on representative material (which may be done on a pilot or laboratory size as opposed to a one-to-one basis).

• On representative material and prior to change Comparability analysis after adjustment
• A statistical analysis of pertinent data, such as current stability studies
• Other empirical or first-principles kinetic models, such as predictive deterioration
• Utilizing the updated Confirmation Stability Study—rather than submitting data as part of the Regulatory change submission—as well as pertinent business information and previous knowledge, including scientific literature. Need to start or finish a continuous long-term, assuming that is relevant. The amended batch undergoes stability testing to guarantee that the permitted shelf life and storage conditions hold true after the implementation of the CMC modifications.

APPENDIX 2: PRINCIPLES OF CHANGE MANAGEMENT

The efficient change control system that supports the tenets of this policy and complies with ICH Q10's fundamental standards is detailed below.

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• Ensures that any modifications are well understood in terms of their scope and effects on various process and control strategy components, including how they will influence both EC and non-EC parts of marketing authorization.
• Apply the process performance and product quality expertise you already possess.
Effective risk management and risk categorization of suggested modifications need scientific validation. The takes into account what could happen if the planned modifications are not carried out.
• Ascertain the data (existing and/or created) that has to be changed and, in turn, the approach, anticipated acceptance standards, and extra performance after the description's execution. Create research methodologies that include, if necessary, product quality monitoring;
• Ensuring, if necessary, submission to the relevant regulator
• Use the established change management procedure to accept or reject the proposed modifications. The involves relevant parties, such as manufacturing, quality, and regulatory parties, among others.
• Confirm that the change's execution is predicated on: Verify that the changes you've made are in line with the relevant PLCM documentation, PACMP, or investigative methodology.
• Assess the produced data to show that the change's goal and acceptability requirements are satisfied.
• Permit the development of risk mitigation strategies in the event that unanticipated hazards are identified or that the acceptance criteria are not followed.

Pharmaceutical Lifecycle Management Challenges
Technology transfer
Integrated quality and risk management
Comprehensive Packaging
Global Product Registration
Intellectual Property Portfolio
Manage complex joint outsourcing networks.

Review of LCAs in the Pharmaceutical Industry
Initially, a thorough assessment of the state of life cycle assessment (LCA) application in the pharmaceutical industry, with a focus on human pharmaceuticals, was conducted to identify common LCA practices within the industry (such as functional unit selection), frequently identified "hotspots" in the drug life cycle, as well as frequently encountered challenges and unmet gaps. The review's findings were intended to provide a foundation for standardized industry-specific regulations—in the form of PCRs—and identify thematic target topics for increasing the use of LCA in the pharmaceutical industry. The focus of the literature review was on life cycle assessment (LCA) case studies of pharmaceutical processes or human pharmaceutical products (i.e., APIs or final drug, including packaging), carried out in or after the year 2000, due to the distinctive features of the pharmaceutical industry (e.g., exceptionally high standards of cleanliness maintained during production) and the relatively recent development of "green pharmacy" practices. Only when a clear downstream use in the pharmaceutical sector was anticipated were life cycle assessments (LCAs) of precursor compounds, such as enzymes, included. Thus, LCAs in the larger area of green chemistry as well as in the healthcare industry as a whole (such as medical equipment) were not included in the search. Search phrases like "Google Scholar's "Cycle Assessment," "LCA," "footprint," and "pharma-cuticle" or "fine Chemical*" combinations have yielded extremely few "pure" pharmaLCA research, with less than 30 papers found so far. There is a peer-reviewed journal available. Many synthetic methods, treatment modalities (such as batch and continuous therapy), formulations, dosage variations, and comparative analysis of packaging alternatives were among the many reasons these life cycle analyses (LCAs) were carried out. Except for a handful, every LCA study that has been looked at to far has used cradle-to-gate analysis, and they have often criticized the lack of adequate data that is available beyond the manufacturing stage.
demonstrates several approaches to defining system boundaries and a generic product system for medicines. The pharmaceutical setting places great importance on the life cycle viewpoint. First, due to the industry's prevalent practice of "outsourcing" certain pharmacological or synthetic stages, or "outsourcing" of effect. Second, the environmental effect of the actual internal synthesis process is often lessened by the environmental impact of upstream activities (such

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as the generation of input chemicals and "background" energy) [10,11]. -Drug lifespan may have a substantial negative influence on the environment, particularly if the analysis takes into account the harmful effects that drugs inject into the sewage system and eventually surface water can have on humans and the ecosystem. To learn more, continue reading below. Section). Pharmaceutical firms should thus strive for a thorough cradle to cemetery examination of Upon deeper examination of the available pharmaLCA, it became evident that the various studies lacked uniformity in several aspects.The choices made about the functional units (FU), system limits, background database use, data quality, effect assessment techniques, and impact categories should be taken into account. Brunet and others. [12] According to De Soeteetal, FU was determined to be 20,840,000 kg of Penicillin V produced during a 20-year period. [13] decided on a once-daily dosage of the anti-HIV medication From PREZISTA as the FU. Nonetheless, the majority of the examined research selected the 1 kg API as the FU. Wernet et al. [10] made the decision to evaluate 16 effect categories (at both average and endpoint levels) using five distinct impact assessment techniques, including Kimetal. [14] We took into account five impact categories in a single manner. Certain methodological disparities amongst pharmaceutical firms' life cycle assessments (LCAs) are sensible and foolish, given the variations in the goals and purview of the evaluated studies and the singular uniqueness of the specific active ingredients / formulations. However, there are significant disparities because of insufficient experience and direction.worries about the use of LCA in the pharmaceutical industry. This often puts the Pharmaceutical LCA's dependability and consistency in danger. For this reason, the pharmaceutical business clearly needs PCR. to direct and encourage LCA in pharmaceutical futures. This section contains preliminary drug PCR considerations.worries over LCA's use in the pharmaceutical sector. This often puts the Pharmaceutical LCA's dependability and consistency in danger. For this reason, the pharmaceutical business clearly needs PCR. to direct and encourage LCA in pharmaceutical futures. This section contains preliminary drug PCR considerations.

Life Cycle Impact Assessment (LCIA) in Pharma-LCAs :

The effect assessment techniques and impact categories used during the LCIA phase of the evaluated pharma-LCAs were very divergent throughout. Nine impact categories/indicators are outlined in a simplified LCA Tool created by the American Chemical Society Green Chemistry Institute (ACS-GCI) Pharmaceutical Roundtable (hereafter referred to as "the Roundtable") to be evaluated in LCAs of drug synthesis methods [11]. displays a preliminary list of eight impact categories that the authors have determined are the most relevant for pharma-LCAs, together with these nine impact categories shown next to the top five evaluated impact categories in the examined pharma-LCAs. The SERUM advisory council, which consists of professionals from academia, politics, and the pharmaceutical business, was consulted in the process of determining the latter list.Notably, impacts—particularly those linked to toxicity—that have been identified as pertinent for the pharmaceutical sector under the SERUM project are seldom taken into account in life cycle assessments (LCAs) and are not advised in the Roundtable's streamlined tool. In light of the intended uses of pharmaceuticals, such as the inhibition or death of microorganisms (antimicrobial), the killing of rapidly dividing cells (anticancer), and the increasing amount of research demonstrating relevant evidence of possible unexpected eco-toxicological effects of APIs (reviewed in [3, 15–17]), it is troubling that none of the pharma-LCAs currently in use take into account the effects of pharmaceutical residues in the environment.The main cause of the discrepancy in recommendations, practice, and perceived importance of the "human toxicity" and "eco-toxicity" categories for pharma-LCAs is a variety of methodological restrictions on toxicity modeling within LCIA, the most notable of which are:

• There are no characterisation factors (CFs) available for medicinal substances.Current Toxicology Models

• Current impact assessment approaches overlook a number of consequences or impact pathways related to medications and their toxic mode of action.

A number of studies have recently updated or calculated new CFs for APIs in the categories of human toxicity, freshwater, marine, or terrestrial eco-toxicity using mostly USEtox, but also EDIP97 and/or USESLCA 2.0 in an effort to address the first constraint and improve the assessment of pharmaceuticals' toxicity in LCIA [18–20].

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Product Category Rules (PCRs) for the Pharmaceutical Industry

A set of products with equal or equivalent functioning is often established by PCR, which broadly compares them. Only PCR for vaccines has been produced so far, despite a convincing debate of a standardized framework in the form of PCR to guide LCA of medicines [25].

Pfizer implemented and released IMPROVAC's Environmental Product Declaration (EPD) based on this PCR. In pig husbandry, this immunological product is utilized in place of physical castration [26]. But after 2015, IMPROVAC EPD is no longer valid.There are no guidelines on how to identify product category for the creation of novel PCRs. as "wide" or "narrow". Put otherwise, the designer has complete control over the "particle size" of PCR. The development of PCR at two distinct levels / particle sizes appears to be viable for the pharmaceutical business, based on feedback gathered in conjunction with pharmaceutical specialists (see figure). 2. In order to determine Broad LCA-modelling requirements that capture some of the industry-wide features, a Generic PCR for the Pharmaceutical sector (also known as "horizontal rules") should first be defined (e.g. The relevance of include treatment operations of solvent waste inside the System bounds). Due to its tendency to provide common modeling rules for quite distinct products of a given sector, as well as its reliance on multiple assumptions and a significantly simplified representation of the industry as a whole, such a generic "frame-PCR" is subject to a considerable degree of uncertainty and inaccuracy.Therefore, specific (or "vertical rules") should be cumulatively developed in a second step that closely aligns with the frame-PCR for: • Pharmaceutical products classified into different drug classes based on the International Anatomical Therapeutic Chemical (ATC) Classification System (product-PCRs); and • Drug manufacturing processes (process-PCRs).In order to evaluate drug alternatives in accordance with the same harmonized scheme based on their shared function (therapeutic purpose) and pharmacological properties, product-PCRs are to be developed for the various drug classes available at the third level of the ATC-code, i.e., the various therapeutic/pharmacological Subgroups of APIs. Process-PCRs would direct LCAs, which have process optimization as their primary goal.

II. CONCLUSION

The demand for more effective medication research and production procedures stems from their complexity.The pharmaceutical business of today. PLM has the ability to increase productivity and lower risk in pharmaceutical manufacturing, even in this very complex environment. The process of developing and overseeing a company's product-related intellectual capital from the idea's conception to its ultimate decommissioning is known as product lifecycle management.

REFERENCES

[1]. Stark J. Product Lifecycle Management: 21st century Paradigm for Product Realisation, SpringerVerlag, New York, 2004.

[2]. Zimmerman T. Implementing PLM across organization – for multi-disciplinary and Crossfunctional product development, PhD thesis, Chalmers University of Technology, Gothenburg, Sweden, 2008.

[3]. Wognum P and Kerssens-van Drongelen I. Process and impact of product data management Implementation. International Journal of Product Development, 2(1–2), 2005, 5–23.

[4]. Challenges in Pharmaceutical Product Life Cycle Management. Available from: Challenges in pharmaceutical-product lifecycle-management#

[5]. Best Practices, LLC blog World-Leading Business Benchmarking Research & Consulting Firm. http://whybenchmarking.com/ Trends in Next generation PLM. Available from: http://blogs.ptc.com/2012/01/26/5-Trendshttp://blogs.ptc.com/2012/01/26/5 trends-in-next- generation Plm/inhttp://blogs.ptc.com/2012/01/26/5- trends-in-next-generation-plm/next-generationPlm/

[6]. Taylor D, The Pharmaceutical Industry and the Future of Drug Development, In Pharmaceuticals In the Environment, Hester, R. E., Harrison,

[7]. R. M., Eds., Issues in Environmental Science and Technology No. 41, The Royal Society of Chemistry, 2015, pp 1–33.

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[8]. Christen V, Hickmann S, Rechenberg B, Fent K, Highly active human pharmaceuticals in Aquatic systems: A concept for their identification based on their mode of action, Aquatic Toxicology, Vol. 96, No. 3, 2010, pp 167–181.

[9]. Arnold, K. E, Brown A. R, Ankley G. T, Sumpter J. P, Medicating the environment: Assessing Risks of pharmaceuticals to wildlife and ecosystems, Phil. Trans. R. Soc. B, Vol.369, 2014.

[10]. Caldwell D. J, Sources of Pharmaceutical Residues in the Environment and their Control, In Pharmaceuticals in the Environment, Hester, R. E., Harrison, R. M., Eds., Issues in Environmental Science and Technology No. 41, The Royal Society of Chemistry, 2015,Pp 92–119.

[11]. Voulvoulis N, Barceló D, Verlicchi P, Pharmaceutical Residues in Sewage Treatment Works And their Fate in the Receiving Environment, In Pharmaceuticals in the Environment, Hester,R. E., Harrison, R. M., Eds., Issues in Environmental Science and Technology No.41, The Royal Society of Chemistry, 2015, pp 120–179.

[12]. Jiménez-González C, Constable D. C, Ponder C. S, Evaluating the "greenness" of chemical Processes and products in the pharmaceutical industry–a green metrics primer, Chemical Society Reviews, Vol. 41, No. 4, 2012, pp 1485–1498.

[13]. Jiménez-González C, Overcash M. R, The evolution of life cycle assessment in pharmaceutical and chemical applications – a perspective, Green Chem., Vol. 16, No. 7, 2014, p 3392.

[14]. Mata T. M, Martins A. A, Neto B, Martins M. L, Salcedo, R, Costa C, LCA Tool for Sustainability Evaluations in the Pharmaceutical Industry, Chemical Engineering Transactions, Vol. 26, 2012.

[15]. Minkov N, Schneider L, Lehmann A, Finkbeiner M, Type III Environmental Declaration Programmers and harmonization of product category rules: Status quo and practical Challenges, Journal of Cleaner Production, Vol. 94, 2015, pp 235–246.

[16]. Wernet G, Conradt S, Isenring H. P, Jiménez-González C, Hungerbühler K, Life cycle Assessment of fine chemical production: A case study of pharmaceutical synthesis, Int J Life Cycle Assess, Vol. 15, No. 3, 2010, pp 294–303.

[17]. Jiménez-González C, Ollech C, Pyrz W, Hughes D, Broxterman Q. B, Bhathela N.,Expanding the Boundaries: Developing a Streamlined Tool for Eco-Footprinting of Pharmaceuticals, Org. Process Res. Dev., Vol. 17, No. 2, 2013, pp 239–246.

[18]. Brunet R, Guillén-Gosálbez G, Jiménez L, Combined simulation–optimization Methodology. To reduce the environmental impact of pharmaceutical processes: Application to The Production of Penicillin V, Journal of Cleaner Production, Vol. 76, 2014, pp 55–63.

[19]. De Soete W, Boone L, Willemse F, Meyer E, Heirman B, van Langenhove H, Dewulf J,Environmental resource footprinting of drug manufacturing: Effects of scale-up and tablet Dosage, Resources, Conservation and Recycling, Vol. 91, 2014, pp 82–88.

[20]. Kim S, Jiménez-González C, Dale B. E, Enzymes for pharmaceutical applications—cradled-gate life cycle assessment, Int J Life Cycle Assess, Vol. 14, No. 5, 2009, pp 392–400.

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