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PATHWAY FOR MARKET AUTHORISATION APPROVAL (MAA) OF BIOLOGICALS IN CHINA

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ABSTRACT

Initial a new biological product from the proof-of-concept stage to the advertising stage is an expensive and intricate process. It involves so many years of study and increase work. To save time and money in bringing products to market, product increase performance should be conducted in unity with the related regulatory requirements. These requests can inform development activities and help you to manufacture a product that meets the regulatory standards of your targeted influence that is, a quality product that is safe and effective for its proposed use. Even though information on the regulatory requirements (e.g., laws, supervision documents, worldwide standards for healthcare product development is eagerly available, navigating the regulatory system is not simple, and it gets even more difficult when dealing with multiple jurisdictions. To help entrepreneurs who are developing healthcare products. The main aim is to help the regulatory understanding that governs product development and certify regulatory observance. It can be used as a starting point to assist you in developing your product. Rather than helping as a compilation of regulations, the guide discusses the primary concepts and principles in regulatory affairs. It gives entrepreneurs a road map to follow.

INTRODUCTION

Developing an innovative healthcare product (biologicals) from the proof-of-concept stage to the marketing stage is an expensive and complex process. It involves many years of research and development work. To save time and money in bringing products to market, product development activities should be conducted in accordance with the related regulatory requirements. Following these requirements can streamline development activities and help you to manufacture a product that meets the regulatory standards of your targeted authority(s) that is, a quality product that is safe and effective for its intended use. Although information on the regulatory requirements (e.g., laws, guidance documents, international standards) for healthcare product development is readily available, navigating the regulatory system is not simple, and it gets even more complex

when dealing with multiple authorities. The Drug Regulatory Authorities are being established in various countries across the globe. The regulatory body ensures compliances in various legal and regulatory aspects of a drug. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate drug development process, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products.

Regulatory authority and organizations are responsible in effective drug regulation required to ensure the safety, efficacy & quality of drugs, as well as the accuracy and appropriateness of the drug information accessible to the public. For accessing the drug related information one needs to know where the regulated information i.e., Act / Regulations / Guidance are parked on the regulatory websites. Then for getting the right information one needs to know the right information parked at particular regulatory websites.

This can be access by the help of "navigation pathway" to get a regulatory approval from particular agency. We need to file an application for a particular product and they are submitted to their particular agencies to market their products and ensure that the products are safe and effective healthcare to individuals around the world. So we need a particular navigation pathway for particular applications or drug products. Implementing a robust regulatory information management (RIM) solution offers a relatively straightforward solution to a myriad of complex issues. Regulatory agencies becoming more safety conscious and demanding more data, regulatory information management (RIM) which leads to increase in demand of navigation pathway. The major challenges of regulatory authorities and organizations around the world are to ensure the safety, quality and efficacy of medicines and medical devices, harmonization of legal procedures related to drug development, monitoring and ensuring compliance with statutory obligations.

Objectives:

- To build a navigation pathway on how to access key regulatory information for biologicals during lifecycle management in China in the form of factsheet that can be used as a ready reckoner.
- To collate data for better analysis & understanding on trend followed in China.
- To recommend on building of a systemic process for collation, analysis, documentation, dissemination, updating & re-validation of information data created for easy & effective LCM & regulatory compliances.

Regulations: National Institutes for Food and Drug Control (NIFDC) is the main role for Regulations of Biologics in China.

- Founded in 1950, National Control Laboratory (NCL)
- Quality control of Food, Functional Food, Pharmaceutical Products, Cosmetics and Medical Devices
- Pharmaceutical Products including Biological Products, Traditional Chinese Medicine, Chemical Drugs, and others

Figure 1: major role in assuring the quality of biological products

APPROVAL PROCEDURE :

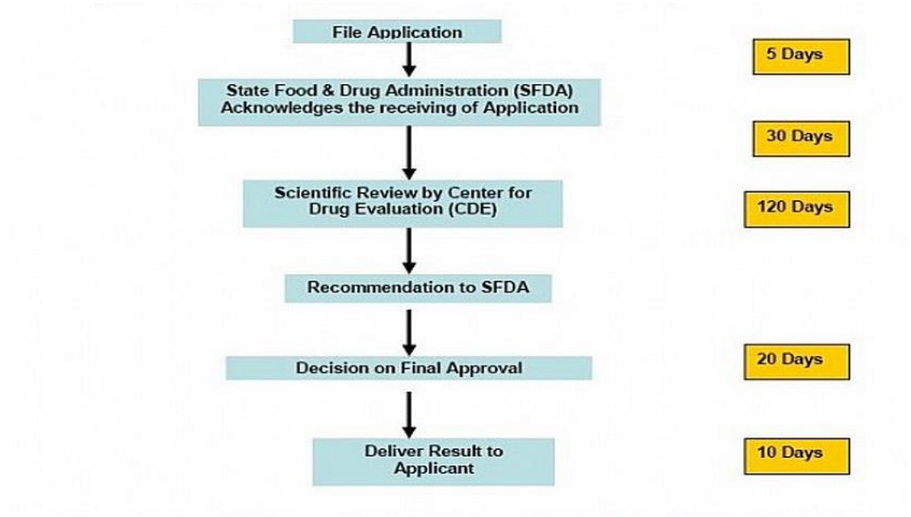

Figure: Approval Procedure forBiologics – China

REVIEW PROCESS:

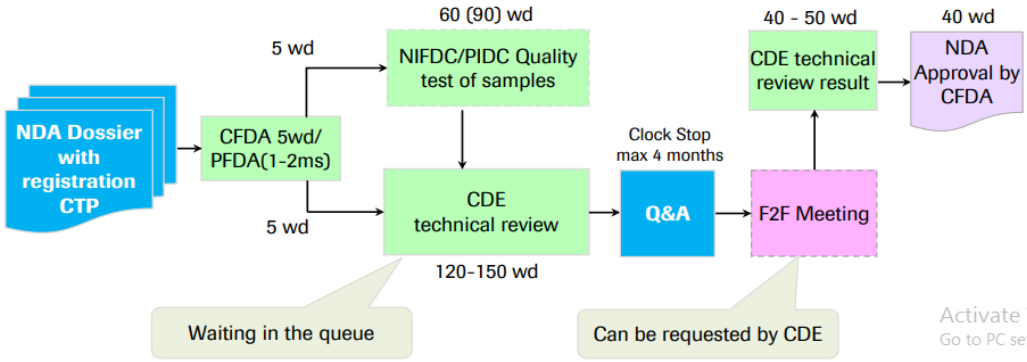

Figure: Review Process for Biologicals- China

SUBMISSION PATHWAY:

LINK:

http://www.cde.org.cn/linshi/regulatEn/Principles%20and%20Procedures%20for%20Drug%20Review%20and%20Evaluation.pdf

CHECKLIST:

http://eng.sfda.gov.cn/WS03/CL0769/98158.html

REFERENCE LINK:

http://www.cde.org.cn/linshi/regulatEn/Principles%20and%20Procedures%20for%20Drug%20Review%20and%20Evaluation.pdf
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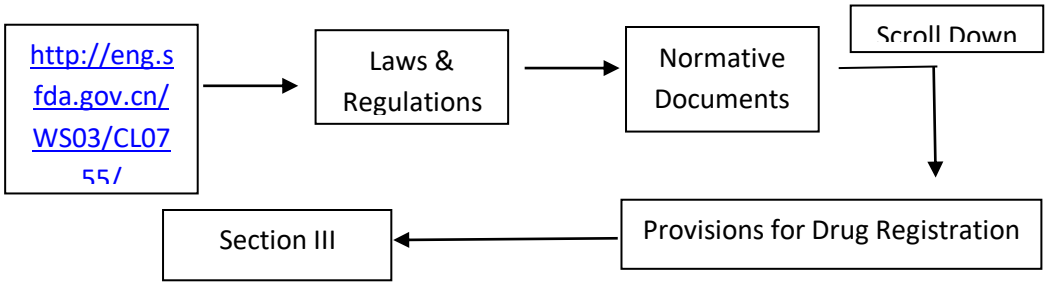

REGULATORY FACTSHEET	
Biologicals	
PRODUCT	Biologics
COUNTRY	China
REGULATORY AGENCY	China Food & Drug Administration
TYPE OFAPPLICATION	Market Authorisation Approval (MAA)

INTRODUCTION:

Biological Product
MAA

Biological Products : 15 different classes

1.A new biological product which not been marketed before in any country.
2. Monoclonal antibody.
3. Gene therapy, somatic cell therapy, and their preparations.
4. Allergen preparation.
5. Multi-component bioactive products extracted from human and/or animal tissues and/or body fluid, or by fermentation.
6.A combination drug preparation which consists of biological products that are already marketed in China.
7. A drug currently marketed outside of China, but has not been marketed in China.
8. Microbial drug preparations which are produced from cell strains that are not yet approved.
9. A drug preparation with a changed structure from an already-marketed product, where this changed new preparation has not been marketed anywhere around the world (changes include chemical modification, amino acid locus mutation or absence, different expression system, etc.)
10. Drug preparation with different manufacturing processes from an already marketed product (different host cells, expression system, etc.)
11. A drug preparation made for the first time with DNA recombination technology. 12. A new drug preparation with a changed administration route from a marketed product, such as non-injection vs. injection or topical vs. systemic administration, where the new preparation is not marketed anywhere in the world.
13. A new drug preparation which has a different dosage form from a drug already marketed in China, but the same administration route.
14. A new preparation with changes in the administration route from a marketed product, but not including cases falling into class 12.
15. Drugs that have already established national specification in China (generics**).**

CONCLUSION:

To establish Navigation Pathway on how to access key regulatory information for LCM of Biologicals in China. A detailed factsheet has been prepared to access the key regulatory information for aforementioned from the various regulatory websites i.e., China.The current study provides a detailed regulatory information management of the act/regulations & guidelines for China.

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