

Type and source of material	Example product	Application of this guide to manufacturing steps shown in grey			
1. Animal or plant sources: non-transgenic	Heparins, insulin, enzymes, proteins, allergen extract, ATMPs immunosera	Collection of plant, organ, tissue or fluid <sup>9</sup>	Cutting, mixing, and / or initial processing	Isolation and purification	Formulation, filling
2. Virus or bacteria / fermentation / cell culture	Viral or bacterial vaccines; enzymes, proteins	Establishment & maintenance of MCB <sup>10</sup> , WCB, MYS, WYS	Cell culture and/or fermentation	Inactivation when applicable, isolation and purification	Formulation, filling
3. Biotechnology – fermentation/ cell culture	Recombinant products, MAb, allergens, vaccines Gene Therapy (viral and non-viral vectors, plasmids)	Establishment & maintenance of MCB and WCB, MSL, WSL	Cell culture and / or fermentation	Isolation, purification modification	Formulation, filling
4. Animal sources: transgenic	Recombinant proteins, ATMPs	Master and working transgenic bank	Collection, cutting, mixing, and / or initial processing	Isolation, purification and modification	Formulation, filling
5. Plant sources: transgenic	Recombinant proteins, vaccines, allergen	Master and working transgenic bank	Growing, harvesting <sup>11</sup>	Initial extraction, isolation, purification, modification	Formulation, filling
6. Human sources	Urine derived enzymes, hormones	Collection of fluid <sup>12</sup>	Mixing, and/or initial processing	Isolation and purification	Formulation, filling
7. Human and/or Animal Sources	Gene therapy: genetically modified cells	Donation, procurement and testing of starting tissue / cells <sup>13</sup>	Manufacture vector <sup>13</sup> and cell purification and processing.	Ex-vivo genetic modification of cells, Establish MCB, WCB or cell stock	Formulation, filling
	Somatic cell therapy	Donation, procurement and testing of starting tissue / cells <sup>14</sup>	Establish MCB, WCB or cell stock	Cell isolation, culture purification, combination with non-cellular components	Formulation, combination, fill
	Tissue engineered products	Donation, procurement and testing of starting tissue / cells <sup>14</sup>	Initial processing, isolation and purification, establish MCB, WCB, primary cell stock	Cell isolation, culture purification, combination with non-cellular components	formulation, combination, fill



# Who Guide To Gmp Requirements

**K Payea**



## **Who Guide To Gmp Requirements:**

The book delves into Who Guide To Gmp Requirements. Who Guide To Gmp Requirements is a crucial topic that must be grasped by everyone, from students and scholars to the general public. The book will furnish comprehensive and in-depth insights into Who Guide To Gmp Requirements, encompassing both the fundamentals and more intricate discussions.

1. This book is structured into several chapters, namely:
    - Chapter 1: Introduction to Who Guide To Gmp Requirements
    - Chapter 2: Essential Elements of Who Guide To Gmp Requirements
    - Chapter 3: Who Guide To Gmp Requirements in Everyday Life
    - Chapter 4: Who Guide To Gmp Requirements in Specific Contexts
    - Chapter 5: Conclusion
  2. In chapter 1, this book will provide an overview of Who Guide To Gmp Requirements. This chapter will explore what Who Guide To Gmp Requirements is, why Who Guide To Gmp Requirements is vital, and how to effectively learn about Who Guide To Gmp Requirements.
  3. In chapter 2, the author will delve into the foundational concepts of Who Guide To Gmp Requirements. This chapter will elucidate the essential principles that need to be understood to grasp Who Guide To Gmp Requirements in its entirety.
  4. In chapter 3, the author will examine the practical applications of Who Guide To Gmp Requirements in daily life. The third chapter will showcase real-world examples of how Who Guide To Gmp Requirements can be effectively utilized in everyday scenarios.
  5. In chapter 4, the author will scrutinize the relevance of Who Guide To Gmp Requirements in specific contexts. This chapter will explore how Who Guide To Gmp Requirements is applied in specialized fields, such as education, business, and technology.
  6. In chapter 5, this book will draw a conclusion about Who Guide To Gmp Requirements. The final chapter will summarize the key points that have been discussed throughout the book.
- This book is crafted in an easy-to-understand language and is complemented by engaging illustrations. It is highly recommended for anyone seeking to gain a comprehensive understanding of Who Guide To Gmp Requirements.

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## **Who Guide To Gmp Requirements Introduction**

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