

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 ⁹	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 ¹⁰ , 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 ¹¹	Initial extraction, isolation, purification, modification	Formulation, filling
6. Human sources	Urine derived enzymes, hormones	Collection of fluid ¹²	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 ¹³	Manufacture vector ¹³ 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 ¹⁴	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 ¹⁴	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

Shasha Hu



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Table of Contents Who Guide To Gmp Requirements

1. Understanding the eBook Who Guide To Gmp Requirements
 - The Rise of Digital Reading Who Guide To Gmp Requirements
 - Advantages of eBooks Over Traditional Books
2. Identifying Who Guide To Gmp Requirements
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Who Guide To Gmp Requirements
 - User-Friendly Interface
4. Exploring eBook Recommendations from Who Guide To Gmp Requirements
 - Personalized Recommendations
 - Who Guide To Gmp Requirements User Reviews and Ratings
 - Who Guide To Gmp Requirements and Bestseller Lists
5. Accessing Who Guide To Gmp Requirements Free and Paid eBooks
 - Who Guide To Gmp Requirements Public Domain eBooks
 - Who Guide To Gmp Requirements eBook Subscription Services
 - Who Guide To Gmp Requirements Budget-Friendly Options

6. Navigating Who Guide To Gmp Requirements eBook Formats
 - ePub, PDF, MOBI, and More
 - Who Guide To Gmp Requirements Compatibility with Devices
 - Who Guide To Gmp Requirements Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Who Guide To Gmp Requirements
 - Highlighting and Note-Taking Who Guide To Gmp Requirements
 - Interactive Elements Who Guide To Gmp Requirements
8. Staying Engaged with Who Guide To Gmp Requirements
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Who Guide To Gmp Requirements
9. Balancing eBooks and Physical Books Who Guide To Gmp Requirements
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Who Guide To Gmp Requirements
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Who Guide To Gmp Requirements
 - Setting Reading Goals Who Guide To Gmp Requirements
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Who Guide To Gmp Requirements
 - Fact-Checking eBook Content of Who Guide To Gmp Requirements
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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