

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

Tao Wei



Who Guide To Gmp Requirements:

Whispering the Techniques of Language: An Mental Journey through **Who Guide To Gmp Requirements**

In a digitally-driven earth where screens reign great and instant communication drowns out the subtleties of language, the profound techniques and mental nuances concealed within words frequently get unheard. Yet, situated within the pages of **Who Guide To Gmp Requirements** a fascinating fictional prize blinking with organic thoughts, lies an extraordinary quest waiting to be undertaken. Penned by a talented wordsmith, this wonderful opus invites visitors on an introspective journey, delicately unraveling the veiled truths and profound affect resonating within the very material of each and every word. Within the psychological depths of the poignant evaluation, we will embark upon a sincere exploration of the book is core subjects, dissect their fascinating writing model, and yield to the strong resonance it evokes strong within the recesses of readers hearts.

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