

| 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 |



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Richard Bailey



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