

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

**Terry C. Jones**



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

## Whispering the Strategies of Language: An Psychological Quest through **Who Guide To Gmp Requirements**

In a digitally-driven earth where screens reign great and immediate interaction drowns out the subtleties of language, the profound techniques and emotional subtleties concealed within phrases usually move unheard. However, nestled within the pages of **Who Guide To Gmp Requirements** a charming literary treasure blinking with raw emotions, lies an extraordinary quest waiting to be undertaken. Written by an experienced wordsmith, this marvelous opus attracts visitors on an introspective journey, lightly unraveling the veiled truths and profound influence resonating within the very material of every word. Within the mental depths with this emotional review, we can embark upon a honest exploration of the book is primary themes, dissect its interesting writing design, and succumb to the powerful resonance it evokes strong within the recesses of readers hearts.

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