

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

**Jessica J Manson**



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

## Unveiling the Power of Verbal Beauty: An Psychological Sojourn through **Who Guide To Gmp Requirements**

In a global inundated with monitors and the cacophony of instantaneous conversation, the profound power and psychological resonance of verbal artistry usually diminish into obscurity, eclipsed by the regular onslaught of sound and distractions. However, located within the musical pages of **Who Guide To Gmp Requirements**, a captivating work of fictional elegance that impulses with raw emotions, lies an wonderful journey waiting to be embarked upon. Composed with a virtuoso wordsmith, that magical opus manuals viewers on a mental odyssey, lightly exposing the latent potential and profound impact embedded within the elaborate internet of language. Within the heart-wrenching expanse with this evocative analysis, we can embark upon an introspective exploration of the book is main styles, dissect its fascinating publishing model, and immerse ourselves in the indelible impact it leaves upon the depths of readers souls.

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