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Guideline on the requirements for quality documentation ...

The principles may also apply to other product types such as proteins and polypeptides isolated from tissues and body fluids. Advanced Therapy Medicinal Products are excluded from this guideline. 1.3. General points concerning all IMPs : IMPs should be produced in accordance with the principles and the detailed guidelines of good

Plant Biotechnology and Genetics: Principles, Techniques ...

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Guidance for Industry - Food and Drug Administration

proteins (e.g., recombinant clotting factors) used at physiologic concentrations or prophylactic vaccines. The process outlined in this guidance pertains primarily to drug products for which

PTC in Manufacture and Testing of Monoclonal Antibody ...

recombinant products are contained in other PTC documents

from CBER (1,2). Some of these recommendations pertaining to

recombinant mAb produced in cell substrates other than hybridomas are