
[General Chapter Prospectus - Cell Banking](#)

Type of Posting: General Announcement

Posting Date: 29–Jul–2016

Expert Committee: General Chapters—Biological Analysis

Input Deadline: August 29, 2016

Current or Proposed Title: TBD (Cell Banking)

Suggested Audience: Biopharmaceutical Industry, Regulatory Agencies, Pharmaceutical scientists, Academicians and Therapeutic Drug Manufacturers

Estimated proposal *PF*: 43(5) [Sep.–Nov. 2017]

Background and Objectives: This new general information chapter is intended to provide knowledge on best practices for preparing, characterizing, and maintaining cell lines used in viral/bacterial vaccine production, manufacturing of recombinant protein therapeutics and cell based assays. In addition, it would include guidance on creating master and working cell banks, characterization and stability of cell banks, clonality and the resupply and qualification of new cell banks. The General Chapter will elaborate on the principles noted in International Conference on Harmonization (ICH) Q5B, ICHQ5D, ICHQ7A and General Chapter <1032> *Design and Development of Biological Assays*. The scope of the General Chapter provides current quality standards for cell banking to establish a controlled and consistent manufacturing process.

Preliminary outline:

Introduction

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- Scope and Background/Supporting Information

General Characteristics Cell Banks / Cell Therapy / Lines

- Organisms / Cells
- GMP considerations and Good Cell Culture Practices
- Safety Considerations
- Qualification of Source / Raw Materials
- History of Cell Line
- Cell bank characterization, Genetic stability and Storage

Cell Banking

- Generation of Cell Banks, Cell line clonality and Strain/Cell Line development
- cGMP Production and Qualification of Cell Banks
- Identity, Purity, Genetic stability and Storage & Stability
- Replacement Cell Banks qualification, characterization and comparability
- Ancillary products
- Cell Banking Quality Considerations

Other USP sources of related information:

- USP General Chapter <1044> Cryopreservation of Cells
- USP General Chapter <1032> Design and Development of Biological Assays

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