



IPRP

International Pharmaceutical
Regulators Programme

2025 Draft Work Plan

Cell & Gene Therapy Working Group (CGTWG)

Date: 16 October 2024

Secretariat: Judith Arcidiacono, FDA, United States

1. KEY MILESTONES AND DELIVERABLES

1.1. Current status of key milestones and deliverables

Past completion date	Objective	Key Milestone or Deliverable
October 2024	Update the collection of regulatory frameworks	First draft completed

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
Ongoing	Participate in ICH Cell and Gene Therapy Discussion Group	The CGTWG proposed topics that will be discussed during in-person ICH meeting in Montreal November 2024
January 2025	Complete regulatory frameworks update	Publish document on IPRP website
March 2025	Complete list of guidance/guidelines	Publish on IPRP website

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
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January 2024	January 2025	Revise and add new frameworks	<ul style="list-style-type: none"> a. Finalize revised framework collection. b. Submit to MC for publication on IPRP website
January 2024	March 2025	Update guidance and guidelines from participating regions	<ul style="list-style-type: none"> a. Compile information into a publishable form. b. Submit to MC for publication on IPRP website
October 2024	March 2025	Update list of approved products in participating regions collected in January 2024	<ul style="list-style-type: none"> a. Update information from participants. b. Compile information into a publishable form. c. Submit to MC for publication on IPRP website