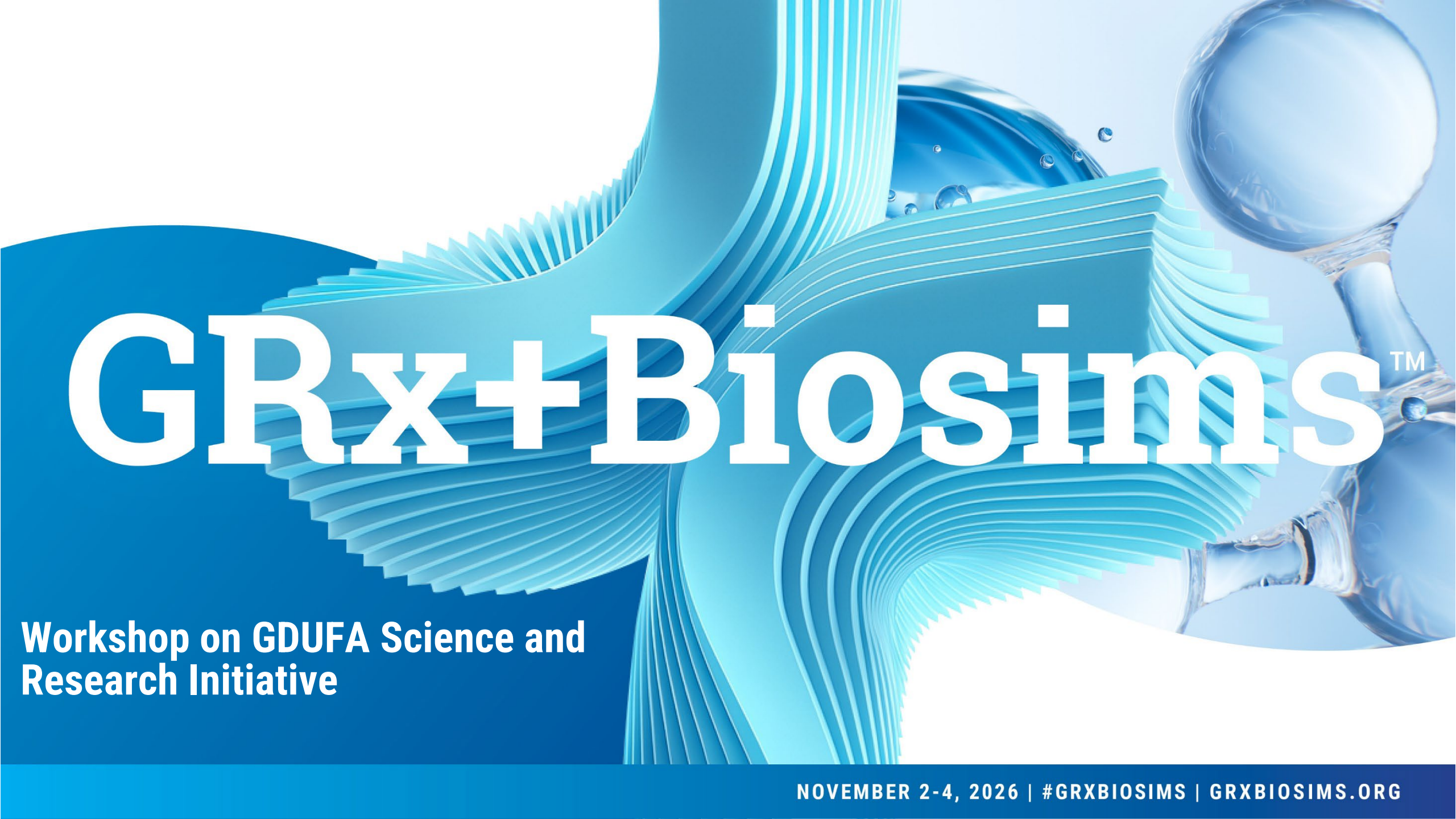

GRx+Biosims™
Workshop on GDUFA Science and Research Initiative
NOVEMBER 2-4, 2026 | #GRXBIOSIMS | GRXBIOSIMS.ORG

How Could Generic Drug Industry Expertise Help To:

2. Assist with Review & Selection of Suitable Research Proposals

3. Provide Technical Guidance on Conduct of Research Activities

4. Support Research Studies with Materials or Study Samples

ADVISE

COLLABORATE

1. Inform the Design of New Research Projects to Optimize Outcomes



5. Collaborate on the Conduct of Multi-Site Research Activities

6. Facilitate Rapid Cycles of Research, Adoption, & Refinement

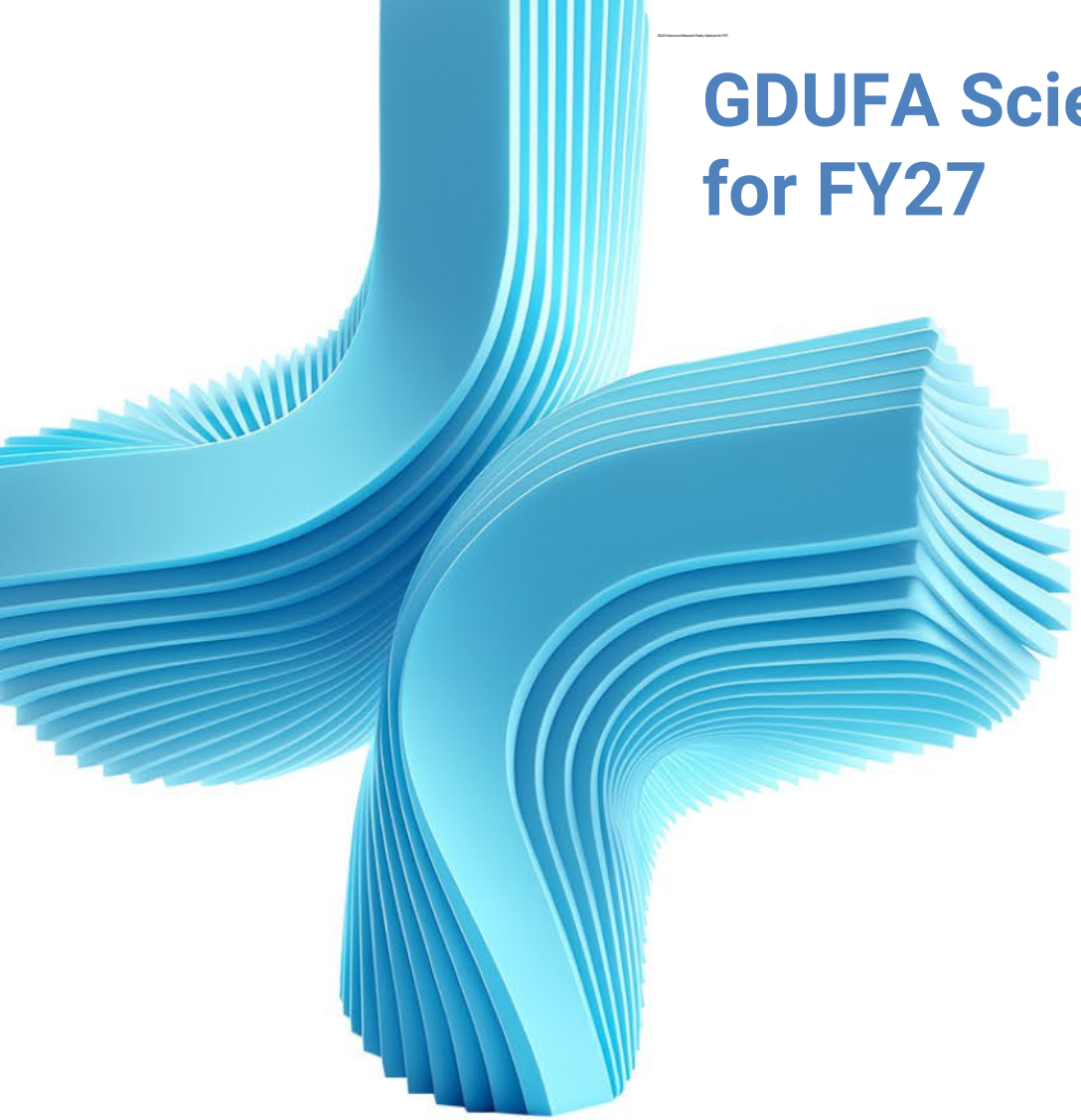
10. Identify Specific Products to Prioritize for PSG Development

APPLY

9. Suggest Technical Content to Enhance the Utility of PSGs

8. Guide Areas Where PSG Revisions Need Clarity vs. Flexibility

7. Optimize Practical Ways to Implement Scientific Insights



GDUFA Science and Research Priority Initiatives for FY27

1. Develop Methods for Generics to Address Impurities such as Nitrosamines

2. Enhance the Efficiency of Equivalence Approaches for Complex Active Ingredients

3. Enhance the Efficiency of BE Approaches for Complex Dosage Forms and Formulations

4. Enhance the Efficiency of BE Approaches for Complex Routes of Delivery

5. Enhance the Efficiency of Equivalence Approaches for Complex Drug-Device Combination Products

6. Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products

7. Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstrations of BE

8. Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools

MEETING SCRIBE WORKFLOW

Record, Transcribe, and Summarize Using iPhone Voice Memos & GenAI

1 START RECORDING



Open the **Voice Memos** app



Tap the **Record** button

Confirm verbal consent from participants.

2 ENABLE TRANSCRIPTION



- Swipe up on screen
- Tap the **Transcript** icon
- Live transcription runs automatically (even if not displayed)

Live transcription may require iPhone 15 Pro or newer.

3 RECORD DISCUSSION



Let recording run during session.

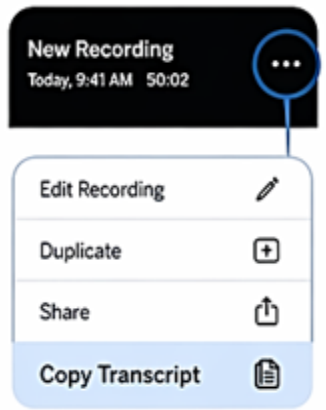
Storage is minimal (~22 MB per ~50 min).

4 STOP RECORDING



Tap **Pause/Stop** when discussion ends.

5 EXTRACT TRANSCRIPT



Tap the three dots menu and select **Copy Transcript**.

Audio file not needed—text only is sufficient.

6 GENERATE SUMMARY



Paste transcript into ChatGPT (or similar tool) with this prompt:

> "You are a meeting scribe. Below is a transcript of a meeting. Please summarize the main discussion points clearly and concisely, focusing only on the key themes, decisions, and action items, while removing filler or unrelated dialogue."

FINAL OUTPUT

KEY THEMES

The most important discussion points captured.

DECISIONS

Agreed-upon decisions or conclusions from the session.

ACTIONABLE ITEMS

Specific next steps, owners, and timelines identified.

BEST PRACTICES

- Test recording and transcription before the session.
- Ensure a quiet environment for best transcription quality.
- Review the summary for accuracy before sharing.

Note: The information in this figure is intended for instructional use to support meeting documentation and does not constitute FDA guidance.

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