

Leveraging AI and Automation to Strengthen Regulatory Processes

November 2, 2026 | 10:45am – 12:00pm

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LEVERAGING AI AND AUTOMATION TO STRENGTHEN REGULATORY PROCESSES

November 2, 2026,
10:45 a.m. - 12:00 p.m.

Moderator

Craig Kiester
Global Head and VP, Regulatory and Quality Policy, Biocon

Panelists

Nimi Chhina
VP, Global Regulatory Affairs Policy & Intelligence (GRAPI), Teva

David Pennington, RN, BSN, MBA
CEO, Dr. Evidence

Andre Raw
Associate Director for Science and Communication
Office of Pharmaceutical Quality Assessment I
Office of Pharmaceutical Quality- Food and Drug Administration

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Panelists

Tao Bai, Ph.D.
Associate Director for Innovation and Partnership
Office of Bioequivalence (OB),
Office of Generic Drugs (OGD),
Center for Drug Evaluation & Research (CDER), FDA

Cristina Ausin, Ph.D., Master Biologist
Office of Therapeutic Biologics and Biosimilars (OTBB)
Office of New Drugs (OND)
Center for Drug Evaluation and Research(CDER), FDA

Breakout Session Description

Regulatory teams often rely on fragmented data sources- labels, clinical trials, literature, and regulatory documents, requiring time-intensive manual synthesis that can delay critical decisions and increase compliance risk. This session will explore how emerging approaches, including fit-for-purpose AI and automation, are being applied to streamline regulatory intelligence workflows, improve data consistency, and enable teams to focus on higher-value scientific and regulatory decision-making.

Session Outline

Nimi – Leveraging AI and Automation to Strengthen the Regulatory Processes

David – Human in command: Practical AI for Regulatory and Labeling Teams

Andre – Elsa: FDA's AI Assistant for Pharmaceutical Quality Assessment

Tao – Enhancing Review Efficiency: FDA Infrastructure Modernization and Standardize Industry Submissions for Abbreviated New Drug Application (ANDA)

Cristina – Leveraging AI and Automation - Biosimilar and Interchangeable Products

Q&A





Leveraging AI and Automation to Strengthen Regulatory Processes

Nimi Chhina

Nov 2, 2026

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CLICK TO ADD CLASSIFICATION IF NEEDED

Regulatory Policy Perspective

Enable innovation without lowering the evidentiary bar

1. Avoid over-regulation

2. Clarify the pathway for generics and biosimilars

3. Make FDA's own AI use transparent



CALIBRATED OVERSIGHT

A practical policy compact

Proportionate oversight
Predictable expectations
Reciprocal transparency

FROM POSSIBILITY TO PRACTICE

Where AI can create value across generic and biosimilar development

01 **Target & portfolio intelligence**

02 **Formulation & process design**

03 **Comparative evidence**

04 **Manufacturing & quality**

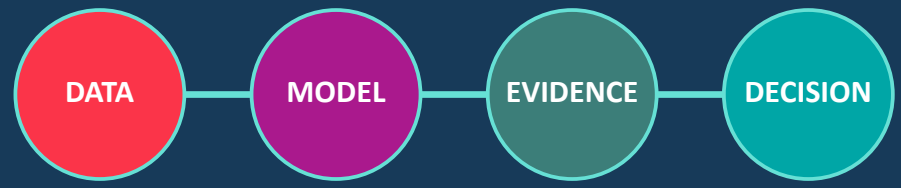
05 **Clinical & real-world execution**

06 **Regulatory operations**

VALUE REALIZED WHEN

USE CASE + DATA + VALIDATION + HUMAN ACCOUNTABILITY

ARE DESIGNED TOGETHER



A disciplined path from data to decision

Useful AI is:
validated, traceable and accountable

Focus first on high-impact high-value use cases with measurable performance and clear responsibility

The goal: faster development and review, while maintaining scientific credibility, data integrity, and patient protection

THANK YOU



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Human in Command: Practical AI for Regulatory and Labeling Teams

Leveraging AI and Automation to Strengthen Regulatory Processes

David Pennington, RN, BSN, MBA | CEO, Dr. Evidence

Where the hours go

01

Label change tracking

Knowing what changed, where and when, across hundreds of labels.

02

RLD monitoring

Watching reference products and working out what each change means for your labeling.

03

Cross-market comparison

Lining up US, EU and other labels section by section to spot the differences.

What AI does well today

AI DOES THE FIRST PASS	PEOPLE MAKE THE CALL
Plain-language search across labels	Pick the answers that matter and check the source
Side-by-side comparisons of sections	Decide which differences are meaningful
Change summaries between versions	Judge impact on your own labeling
First-draft notes for the team	Edit, approve and own what goes forward

Guardrails that keep people in command

Every answer shows its source

Cited back to the label and section it came from.

AI is a choice, account by account

Teams decide which AI features are switched on.

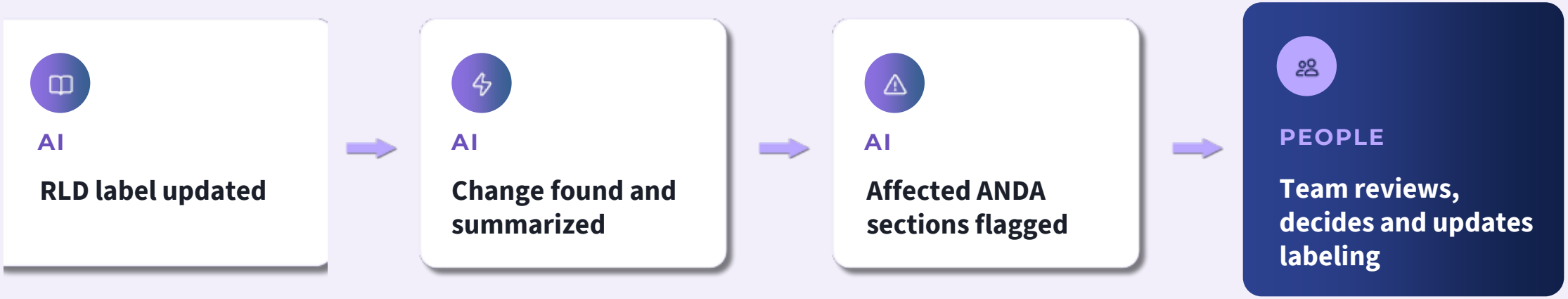
Experts sign off

Nothing reaches a submission without human review.

Clear lines on what AI does not do

It informs decisions. It does not make them.

An example: reference label changes



> The win is not speed alone. It is that nothing gets missed and the expert spends time on judgment, including carve-outs.

Three things to take back to your desk

1. **Start with the work you already double-check**
   Low risk, fast payback and your team already knows what right looks like.

2. **Insist on a source behind every answer**
   If you can't trace it to the label, don't use it.

3. **Decide who holds the switch**
   Set which AI features are on and who signs off before you scale.

QUESTIONS

Thank you. Let's open it up.

David Pennington, CEO, Dr. Evidence

dpennington@drevidence.com | drevidence.com | Booth 7

Elsa: FDA's AI Assistant for Pharmaceutical Quality Assessment

Andre Raw, Ph.D

Associate Director for Science and Communication
Office of Pharmaceutical Quality Assessment I
Office of Pharmaceutical Quality- Food and Drug Administration

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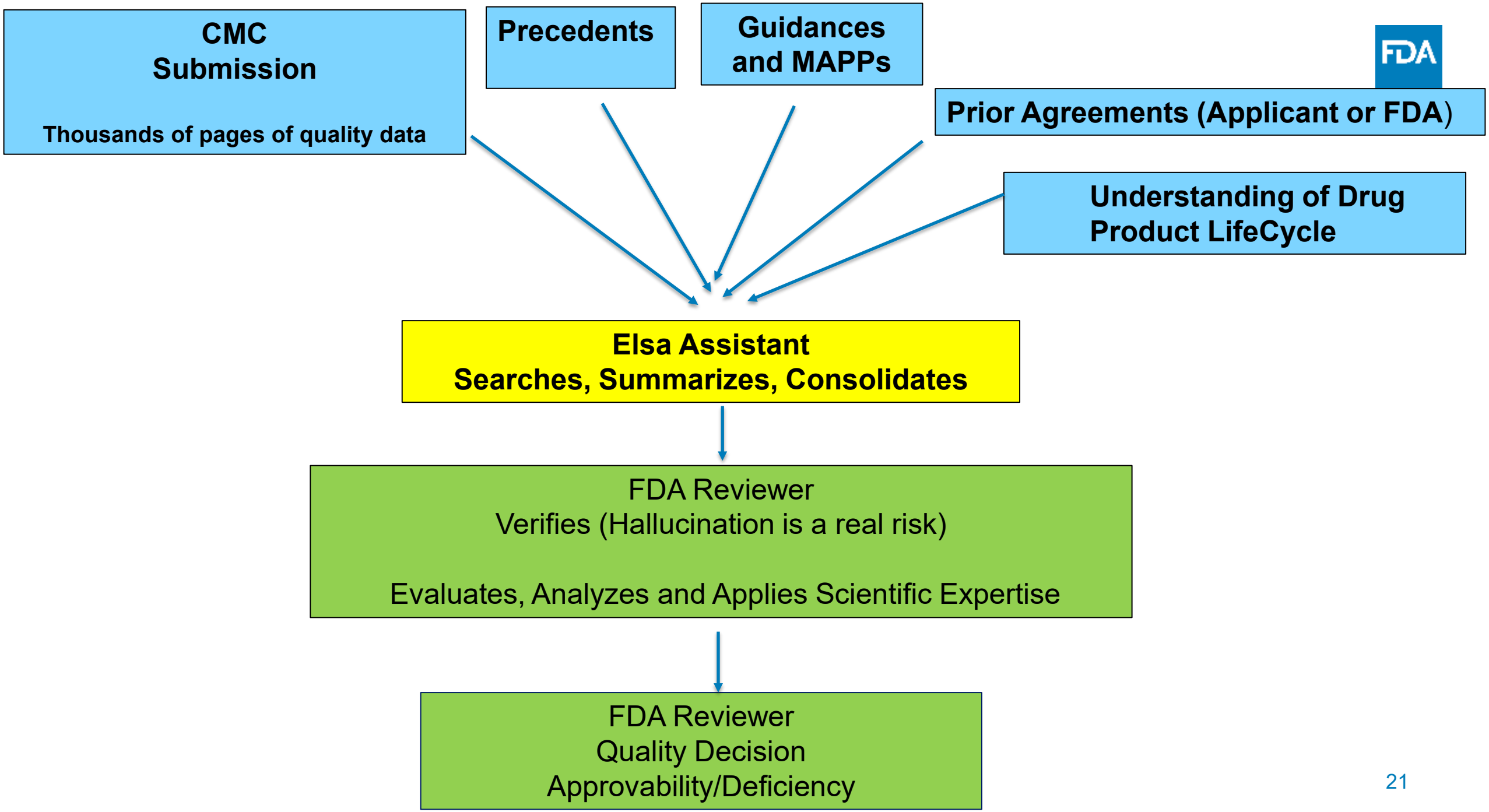
What is Elsa?

- Elsa is FDA's internally deployed generative AI assistant, launched June 2, 2025.
  - Upgraded to Elsa 4.0 (May 2026), integrated with HALO —FDA data sources.
  - Secure GovCloud environment: data stays within FDA; never used to train the AI model.
  - Available to scientific reviewers, investigators, and FDA staff across all Centers.
  - Core principle: Elsa assists the reviewer — all regulatory decisions remain with qualified FDA staff.

The Challenge: Pharmaceutical Quality Review

Quality (CMC) review is data-intensive, document-heavy, and scientifically complex

- NDA/ANDA submissions contain thousands of pages of CMC data covering drug substance, drug product, manufacturing, and controls
- Submissions must be reviewed in the context of the drug product lifecycle that span original submission, amendments, supplements, and prior agreements or marketing commitments
- Reviewers must assess specifications, analytical methods, stability data, manufacturing process descriptions, and more — often under tight timelines.
- Requires considering applicable guidance's and MAPPs
- Requires considering various precedents
- There is a growing need for tools that help reviewers manage volume without compromising scientific rigor


CMC
Submission
Thousands of pages of quality data
Precedents
Guidances
and MAPPs
FDA
Prior Agreements (Applicant or FDA)
Understanding of Drug
Product LifeCycle
Elsa Assistant
Searches, Summarizes, Consolidates
FDA Reviewer
Verifies (Hallucination is a real risk)
Evaluates, Analyzes and Applies Scientific Expertise
FDA Reviewer
Quality Decision
Approvability/Deficiency

Elsa LLMs as a Tool to Enhance Communication

- **Four-Part Harmony is an FDA communication** framework (MAPP 5016.8) that ensures all quality-related communications address four essential components:

  - What was provided? – Acknowledgment of the applicant's submission
  - What is the issue? – Identification of deficiencies or concerns
  - What is needed? – Clear request for additional information or action
  - Why is it needed? – Justification with regulatory or scientific rationale

- Consistent application of these four elements helps reduce back-and-forth with applicants and improves communication quality across review disciplines.

How the Four-Part Harmony Elsa Tool Works

- The tool operates through three sequential procedures and produces two key outputs:
  - **1. Audit:** Silently evaluates each draft IR against Four-Part Harmony guidelines and assigns a star rating (⭐ to ⭐⭐⭐⭐) based on how many elements are recognized.
  - **2. Modification:** Generates revised language for items rated below four stars, incorporating missing harmony elements while minimizing changes to the original text.
  - **3. Verification:** Creates a comprehensive table with original items, star ratings, revised versions with change tracking (underline = additions, strikethrough = deletions), and color-coded harmony element highlights.

- *Note: All suggested revisions must be reviewed by the responsible reviewer for technical and regulatory accuracy. The tool enhances communication structure but does not replace reviewer expertise.*

Key Takeaways

Elsa is a powerful tool — used responsibly, it meaningfully enhances FDA's pharmaceutical quality review capacity.

– Elsa 4.0 is integrated with HALO, giving reviewers AI-assisted access to FDA data sources.

– Elsa is an assistant to aggregate information for the assessor.

- Elsa LLMs are quite useful tool to enhance communication to industry

Elsa assists the reviewer
All regulatory/scientific decisions remain with qualified FDA staff.

Enhancing Review Efficiency: FDA Infrastructure Modernization and Standardize Industry Submissions for Abbreviated New Drug Application (ANDA)

Tao Bai, Ph.D.

Associate Director for Innovation and Partnership

Office of Bioequivalence (OB), Office of Generic Drugs (OGD), Center for Drug Evaluation & Research (CDER), FDA

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Building the data foundation for a modern, AI-ready FDA

HALO

- Released in May 2026
- Harmonized AI & Lifecycle Operations for Data
- A data platform consolidation initiative (>40)
- Serves as FDA's enterprise data platform
- Onboarded submission and review data
- Supporting data-readiness analysis

Structure Review

- KASA (Knowledge-Aided Assessment and Structured Application)
- GDSA (Generic Drug Structured Assessment)
  - Bioequivalence
  - Labeling

FDA Elsa and Elsa Adoption

Elsa

- Elsa 4.0 (released in May 2026)
- The most transformative upgrade for Elsa
- Elsa is not connected to the internet
- FDA staff are involved at every stage of the AI work process in Elsa

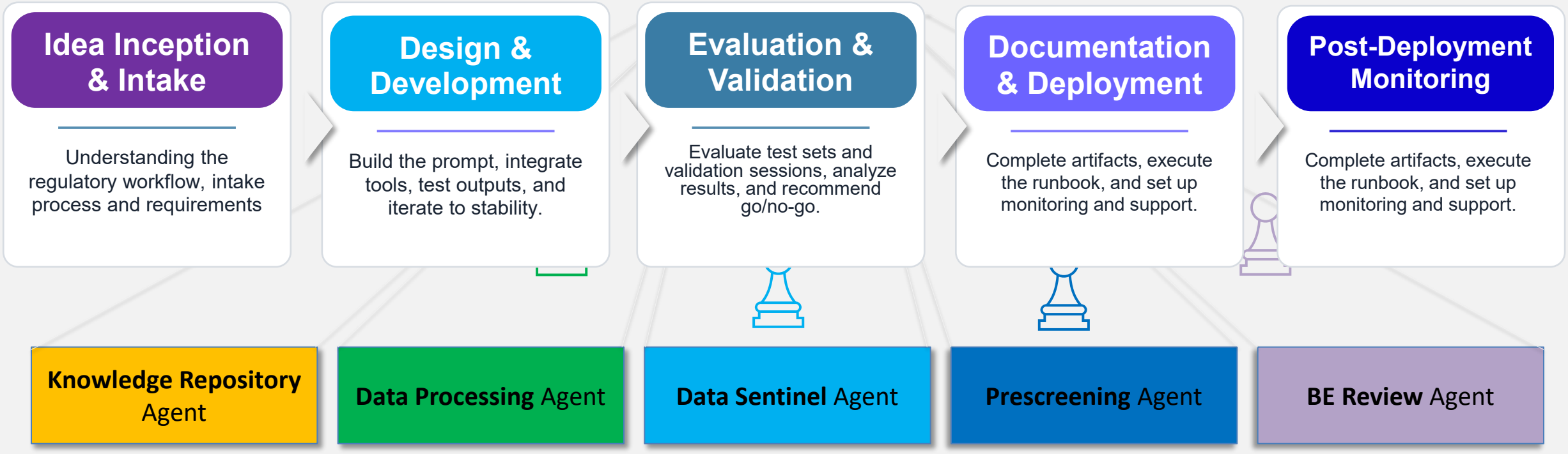
AI Adoption

- Comparative AI adoption surveys in Office of Bioequivalence/OGD between February (n=91) and September (n=91) in 2026
- Staff familiarity with FDA Elsa increased by 23.6%.
- Regular Elsa use increased from 33.0% to 47.8%.
- Daily integrated Elsa use increased from 4.4% to 23.2%—more than fivefold.
- 90% of respondents reported increased use of Elsa and other AI tools compared with the beginning of the year.

OB ■ AI ■ NEXBE

NEXBE – Next Generation Bioquivalence

– A Multi-Lane Portfolio Roadmap for Office of Bioequivalence



Standardize ANDA submission in GDUFA IV

- **IV. ADDITIONAL PROGRAM ENHANCEMENTS (*page 30*)**
- C. Standardizing Information in ANDA Submissions
- 1. To improve review efficiency, FDA will provide or update standard tables and format information for applicants to use when submitting the following data in an ANDA:
  - a. Bioequivalence Study Summary Tables
  - b. Bioequivalence Site Information
  - c. Drug Substance and Impurity Structures
  - d. Pharmacokinetic Study Data from individual subjects
- 2. FDA will provide external training on each of these topics and industry will aspire to submit data using the provided tables and to follow provided format recommendations to enhance the efficiency of the ANDA review process.

U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research

fda.gov/biosimilars

LEVERAGING AI AND AUTOMATION - BIOSIMILAR AND INTERCHANGEABLE PRODUCTS

GrX + Biosims

November 2, 2026

Cristina Ausin, Ph.D., Master Biologist
Office of Therapeutic Biologics and Biosimilars (OTBB)
Office of New Drugs/Center for Drug Evaluation and Research
US Food and Drug Administration

Potential Uses of AI for Regulatory Review

Search and Discovery	Analysis and Insights	Drafting and Documentation
Enhanced Search	Data Analysis	Document Creation
Submission Review	Data Visualization	Enhanced Writing

AI as an Assistive Tool: Important Considerations

- AI does **NOT** replace FDA staff or reviewers.
- AI is an **optional, assistive** tool to support and streamline the review process.
- AI outputs are **not** 100% reliable; human verification to ensure accuracy and mitigate risks (e.g., factual errors or omissions) is required.

Potential Uses for Biosimilar Review

- Automating entry of content in reviews
  - Administrative application details from form 356(h) and cover letter
- Preparation of summaries of meeting agreements
- Generation of tables of studies submitted and reviewed

Potential Uses for Comparative Analytical Assessment Review

- Extract and organize data from the application
  - Compile all quality attributes analyzed and analytical methods used
  - Ensure consistency with advice provided during development
  - Organize CAA results to facilitate their evaluation and documentation of conclusion