# GDSA-BE: Modernizing Bioequivalence Assessment for Abbreviated New Drug Applications

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# We Are OGD

***Ask me why...***

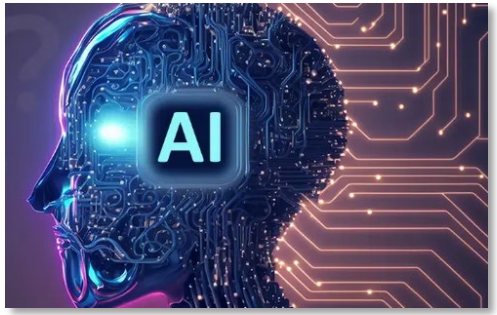
"I make sure that the **generic** drug and the **brand** drug work **the same**."

"The first time I was able to buy my son's inhaler as a generic and realized that my out of pocket dropped, I cried and was able to breathe a sigh of relief."

www.fda.gov

# Need for Modernization - Technology Advancement

## Outside World





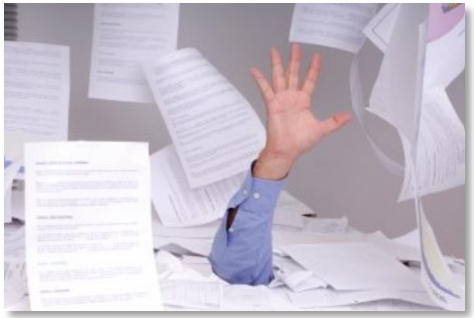

**GDSA-BE**

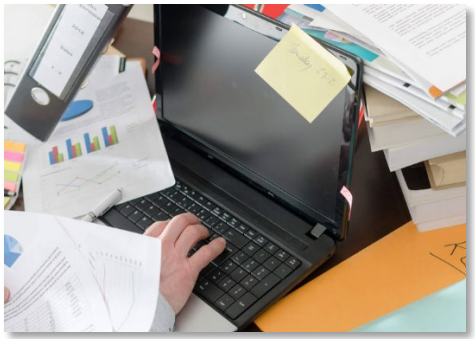
**(Generic Drug Structured Assessment – Bioequivalence)**

Consistency | Standardization | Efficiency

Knowledge Management

## Regulatory Review





# Need for Modernization- Challenges with Current Process

**External**

- Need for a more streamlined assessment process to better meet GDUFA* goals
- Increased expectations from Congress, generic applicants, and the public

**Assessment**

- A freestyle narrative-based bioequivalence (BE) assessment, which is in place for decades
- Labor intensive tasks to process data, conduct data analysis, and extract and supply standard information to the review templates
- Lack of a better practice for knowledge sharing and knowledge management

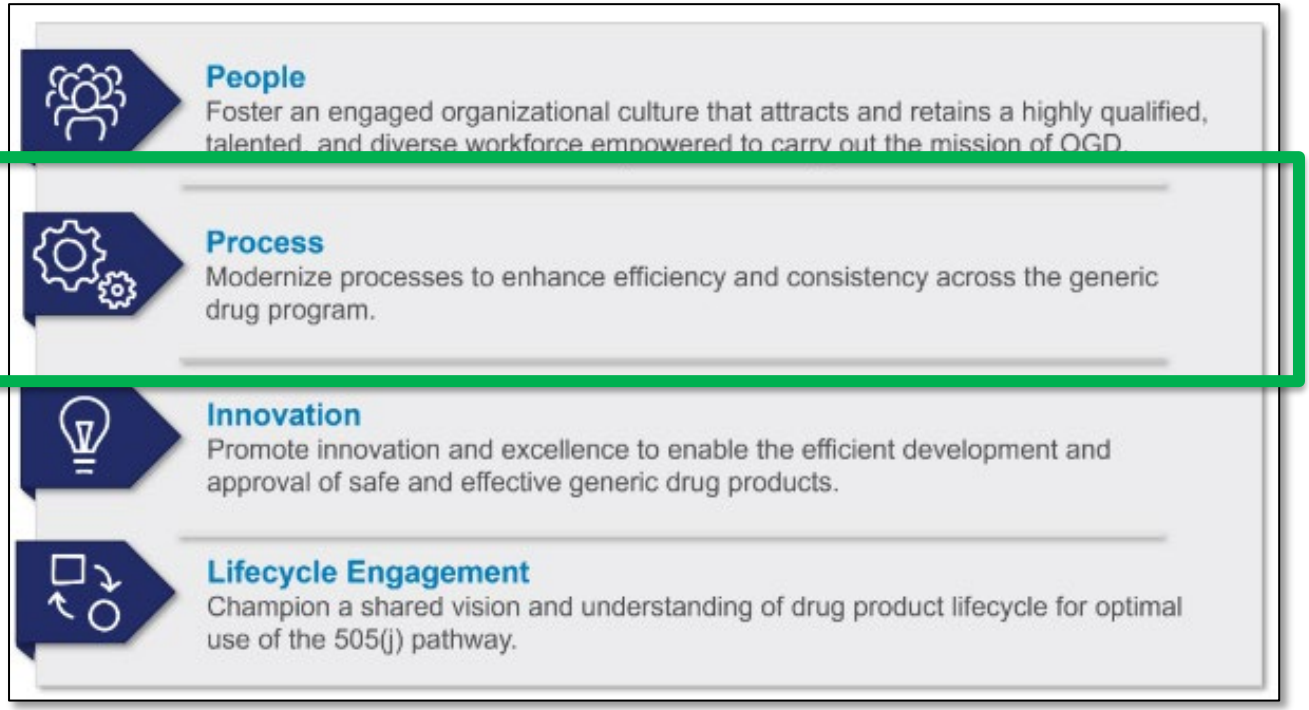
**Application**

- Needs for standardized and structured data submission in ANDA applications

** Generic Drug User Fee Act*

# OGD Strategic Priorities (2023 – 2028)

## Modernizing the Generic Drug Program




*from Ilun Murphy's keynote at the AAM GRx + Biosims 2023 conference*

# GDSA-BE


## Modernizing the BE Assessment Process:

In 2023, OGD launched a new structured BE assessment tool – the Generic Drug Structured Assessment for Bioequivalence (GDSA-BE) – for two-way crossover in vivo pharmacokinetic (PK) BE studies for oral solid dosage form drug products. This tool officially signaled the change of bioequivalence assessment from narrative review to structured data with dynamic, interactive, and integrated collaboration capabilities. GDSA-BE is a BE assessment tool to enable a streamlined and efficient BE assessment and a powerful knowledge management tool, which aids consistent and well-informed regulatory decision making with direct access to multiple subject databases.

# OGD Generic Drug Structured Assessment (GDSA)

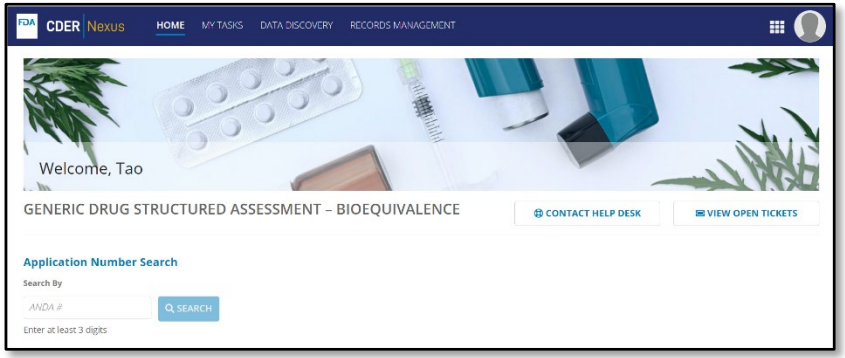
## -OGD Structured Review Templates in NEXUS (Appian) – *Enterprise-level solution*

Modernization of bioequivalence assessment from unstructured narrative *to* structured data with dynamic and interactive collaboration capabilities utilizing an integrated system.

**DIVISION OF BIOEQUIVALENCE REVIEW**

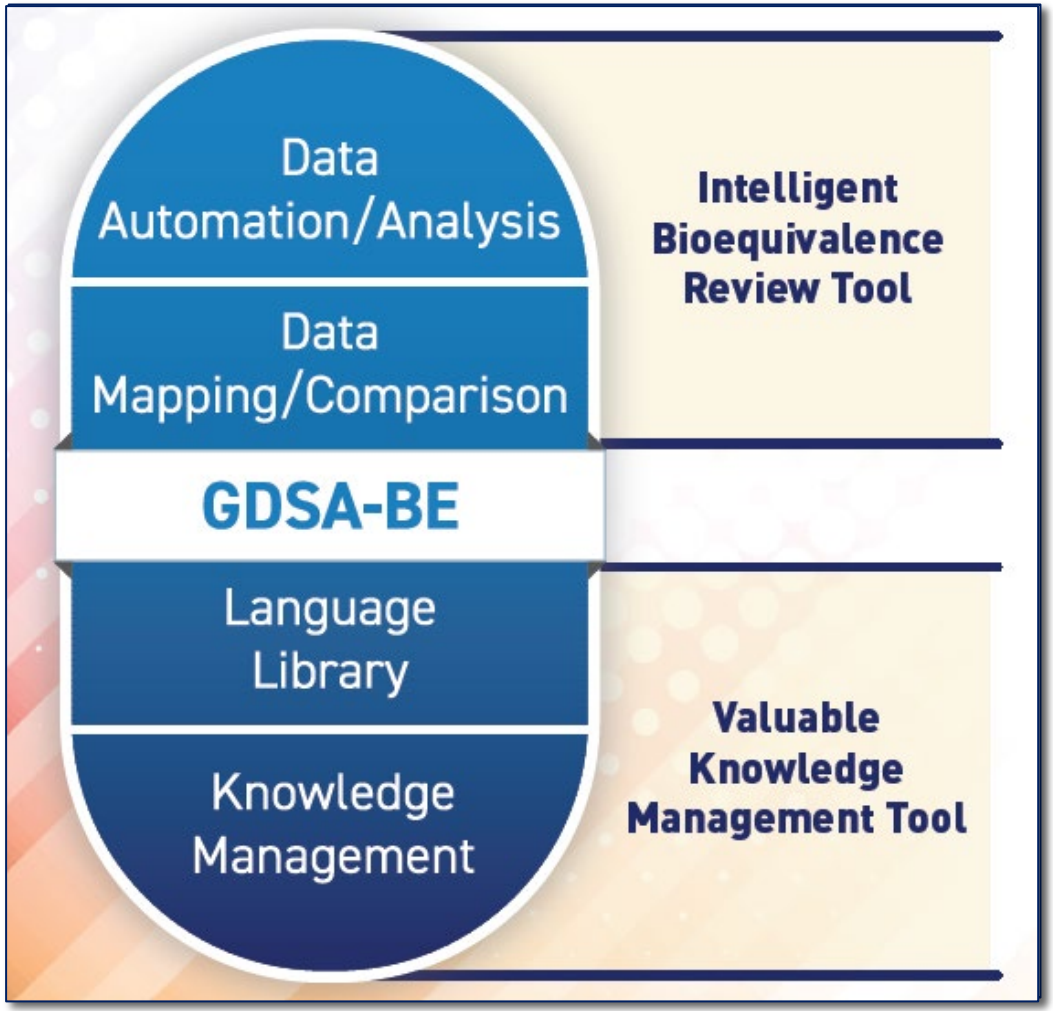
| | |
|---|---|
| ANDA No. | |
| Drug Product Name | |
| Strength(s) | |
| Applicant Name | |
| Applicant Address | |
| US Contact Name and US Mailing Address | |
| US Contact Telephone Number | |
| US Contact Fax Number | |

Current BE Review- Unstructured Narrative




**GDSA-BE Review**-Structured and Interactive

# GDSA-BE Benefits



# Where is GDSA-BE Today

| Releases | Assessments | Implementation |
| --- | --- | --- |
| • V(1.0) Released on 12/12/2022<br>• V(1.1) Released on 9/18/2023<br>• V(1.2) Released on 3/25/2024 | • ~60 ANDA assessments completed in the system | • Implemented **fully** in Office of Bioequivalence |

# Challenge Question

GDSA-BE *(Generic Drug Structure Assessment – Bioequivalence)* tool is (a):

A. Generic Drug BE Review Tool
B. BE Knowledge Management Tool
C. Both

# Summary

- Generic drug bioequivalence assessment is entering a ***new era*** – GDSA-BE (Generic Drug Structured Assessment – Bioequivalence)
- GDSA-BE is both an intelligent review tool and a valuable knowledge management tool
- GDSA-BE enables an efficient and standardized BE assessment process and empowers an informed and consistent regulatory decision-making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