
BPS Negative Decisions Analysis

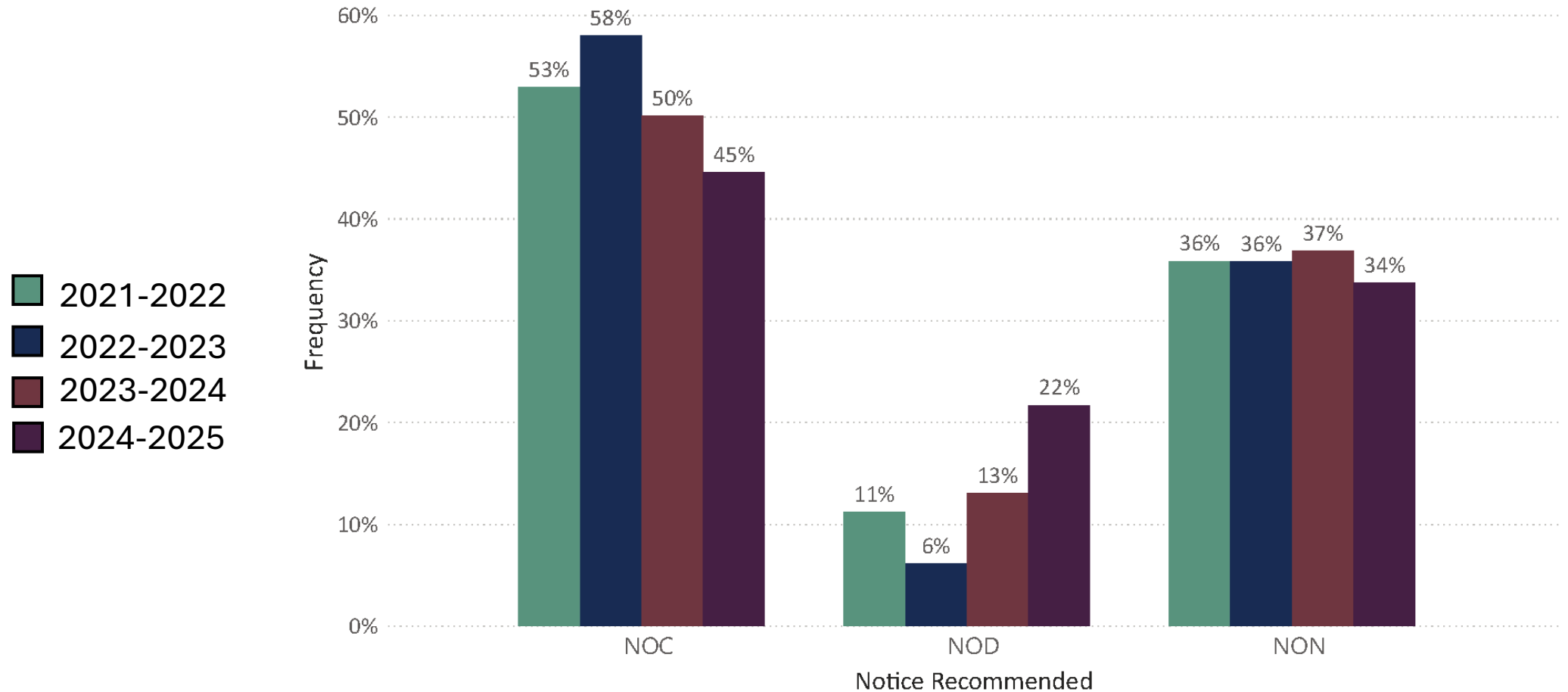
October 2024

Susan Lum, BPS Manager

Overview

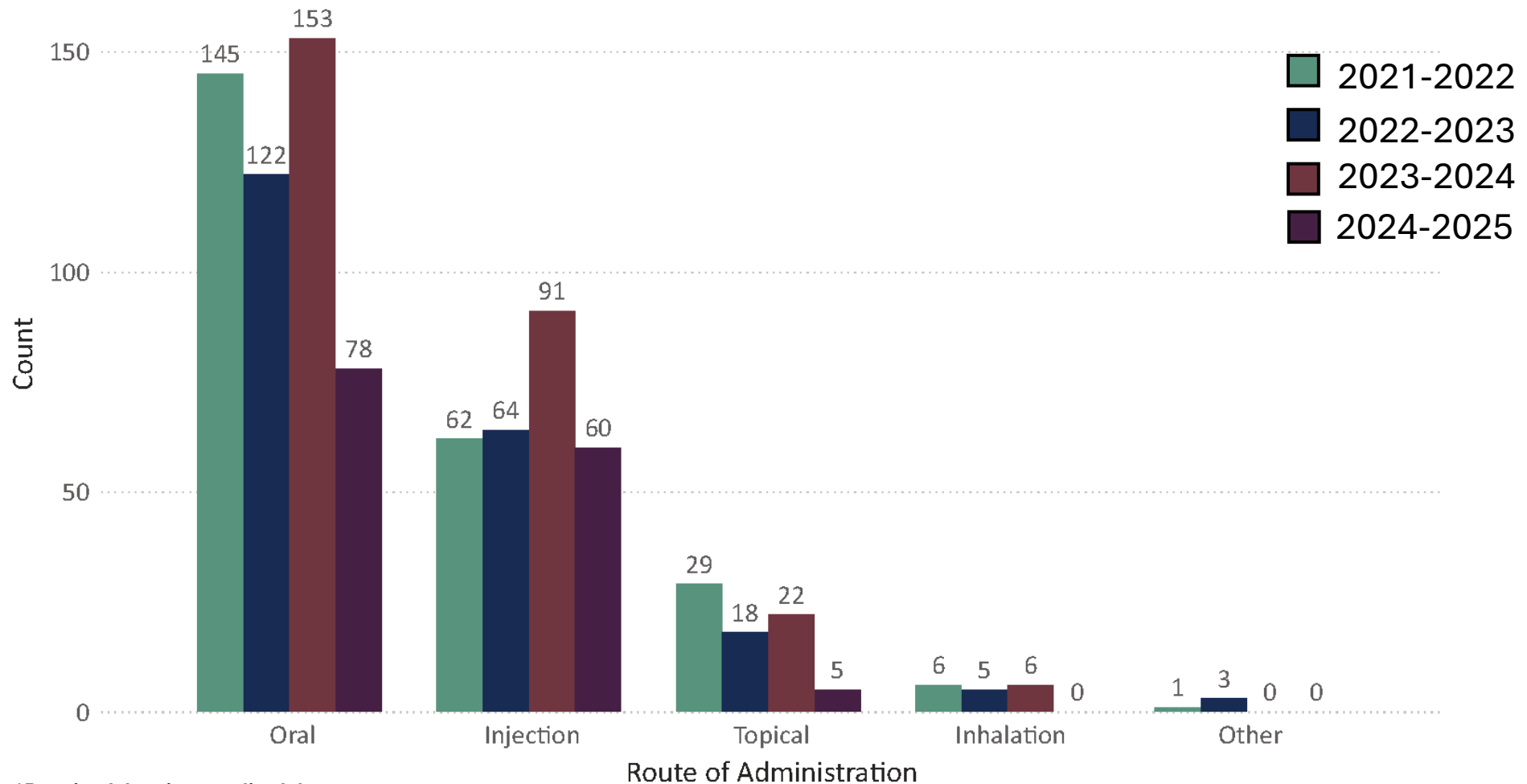
- Negative decisions for three fiscal years (FY) issued by **BPS Quality Divisions** were analysed:
 - April 1, 2021 - March 31, 2022
 - April 1, 2022 - March 31, 2023
 - April 1, 2023 – March 31, 2024
 - April 1, 2024 – September 30, 2024

Distribution of Recommendations Issued



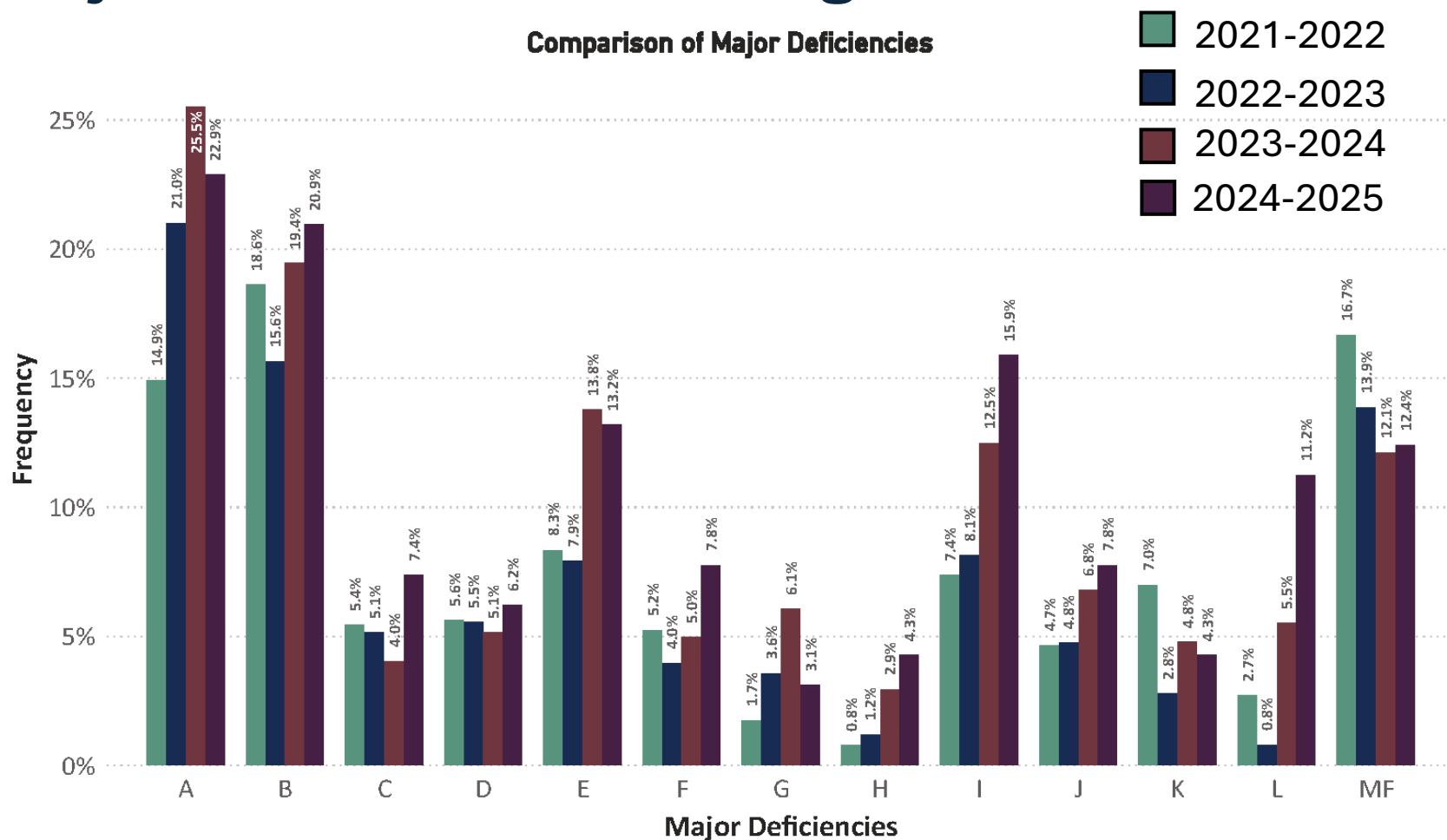
*Received data is unaudited data

Distribution of Negative Decisions: Route of Administration



*Received data is unaudited data

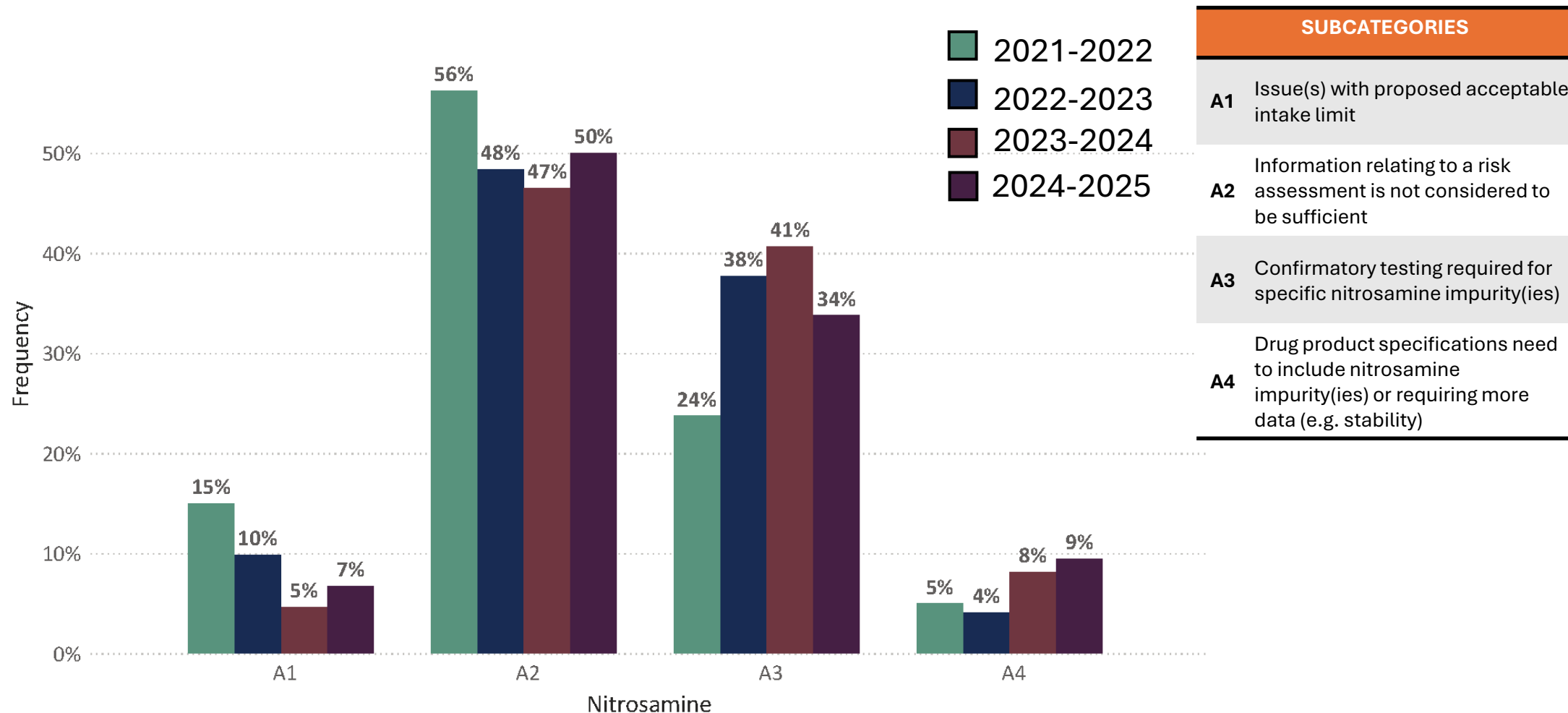
Distribution of Negative Decisions: Major Deficiencies/Categories



CATEGORIES	
MF	Major Objection with ASMF
A	Nitrosamine issues
B	Biowaiver not granted
C	Method validation issues
D	Control of impurities
E	Issues with stability studies
F	Manufacturing process issues
G	Sterilization process validation issues
H	Condition of use in PM issues
I	Container Closure System (CCS) Issues
J	Dissolution issues
K	Negative Decision by other
L	Drug product missing data/studies/specification issues

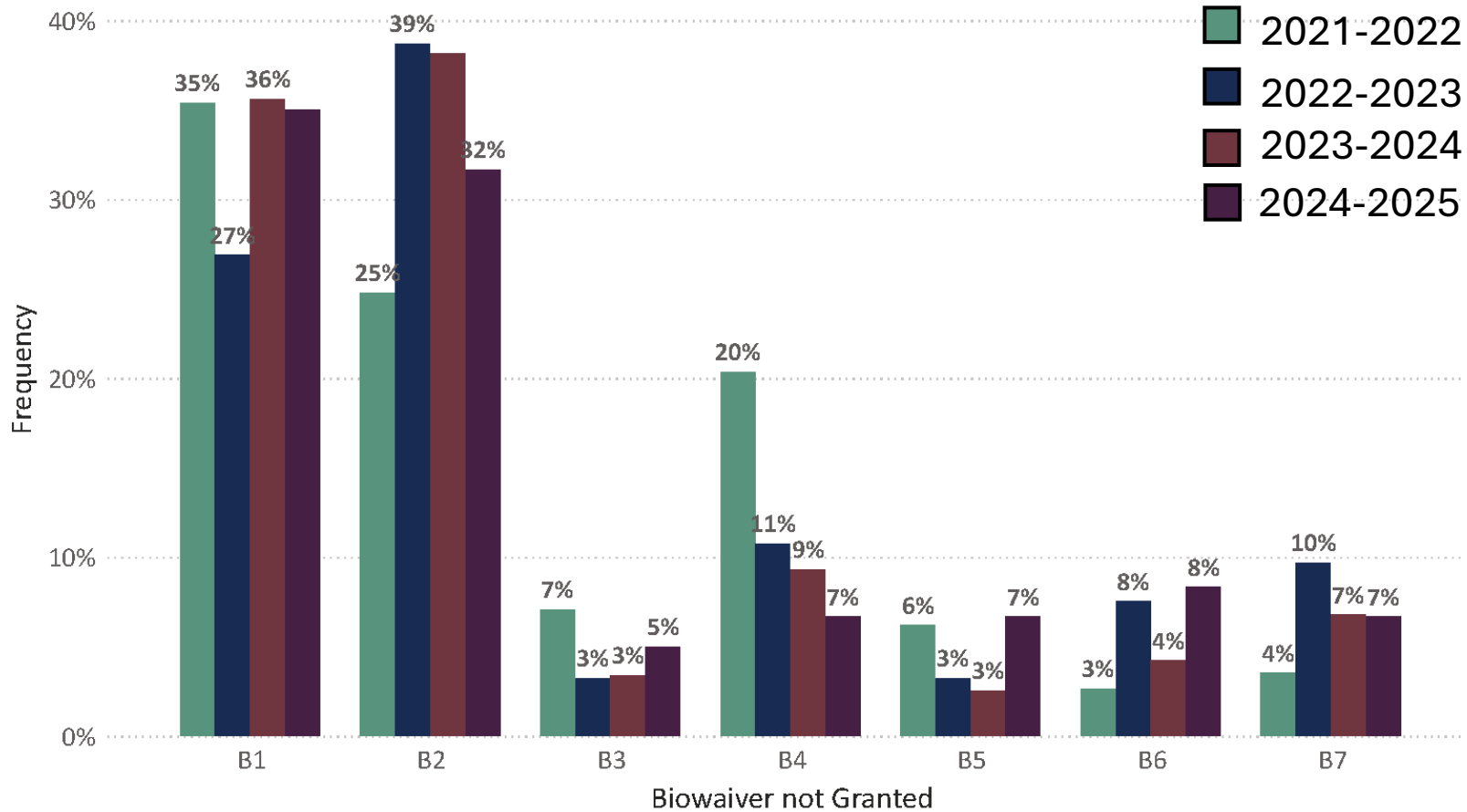
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Nitrosamines: Deficiencies



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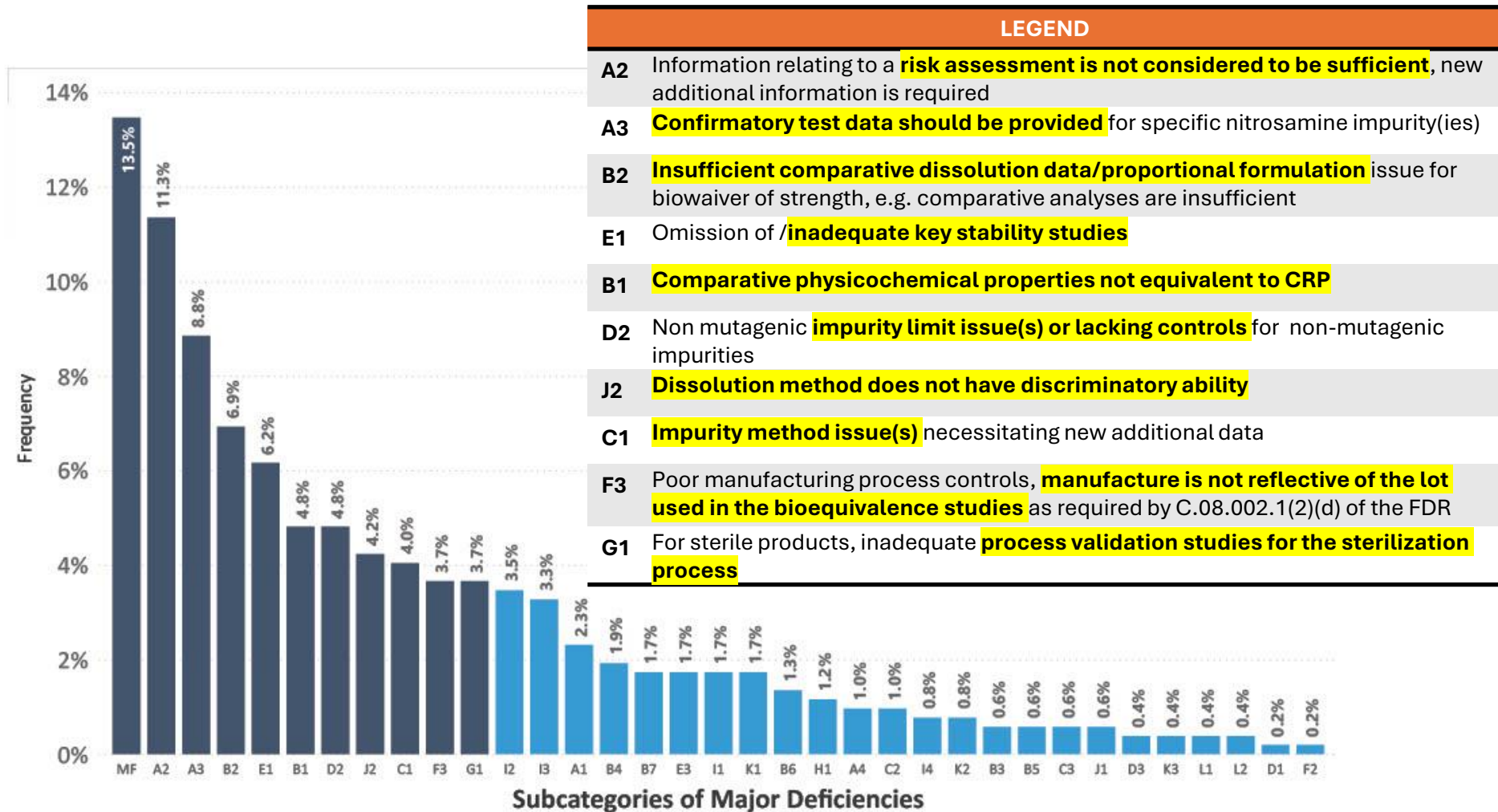
Biowaiver: Deficiencies



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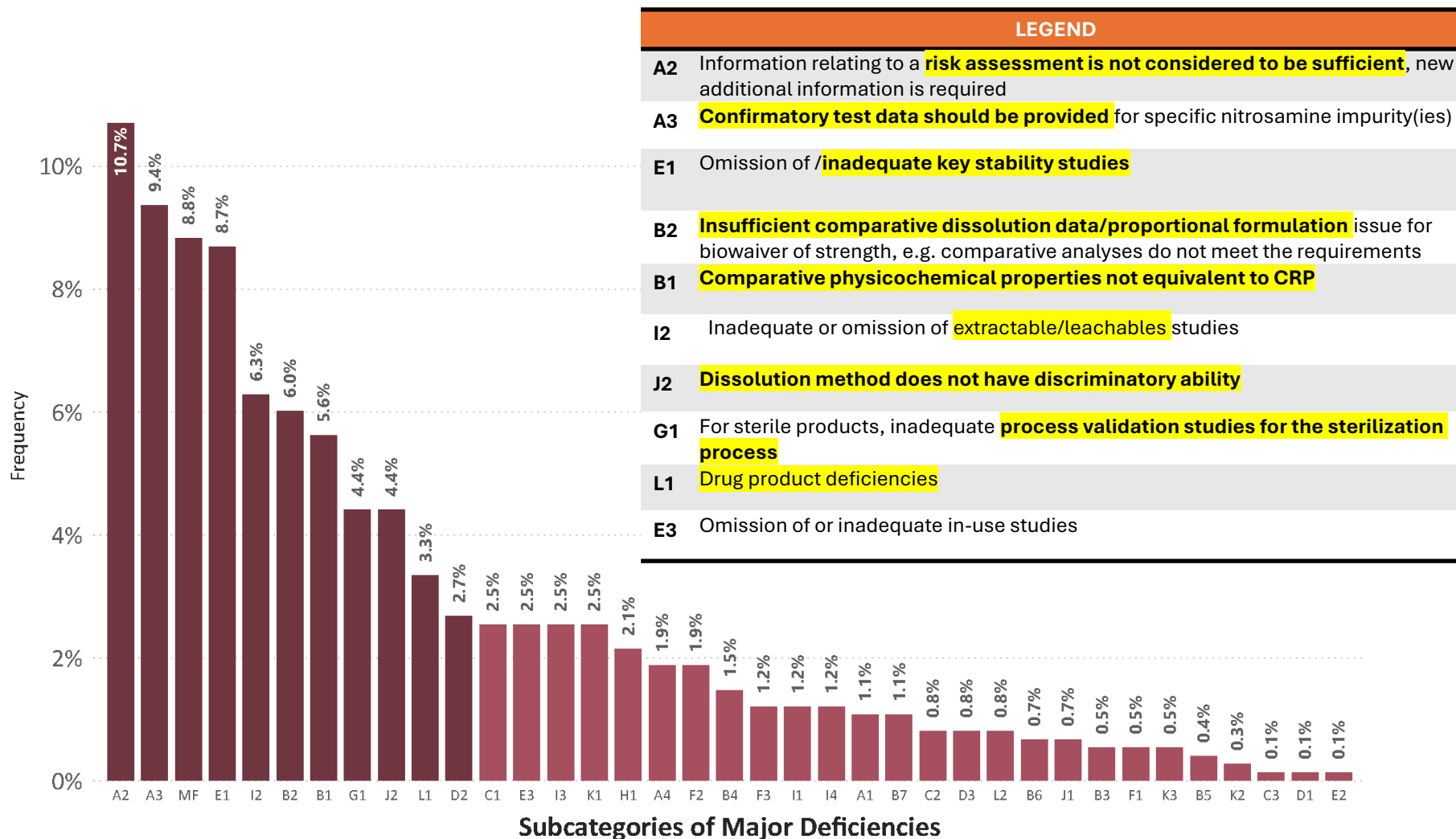
LEGEND	
B1	Comparative physicochemical properties not equivalent to CRP
B2	Insufficient comparative dissolution data/proportional formulation issue for biowaiver of strength
B3	Omission of key test data/studies
B4	Poor compatibility studies, safety and efficacy concerns
B5	Not pharmaceutical equivalent or the drug product is not reflective of the lot used in the bioequivalence studies
B6	BE study not accepted by DBE e.g. deficiencies at the site
B7	Foreign Reference Product (FRP) issue

Top 10 Comments for 2022-2023 FY



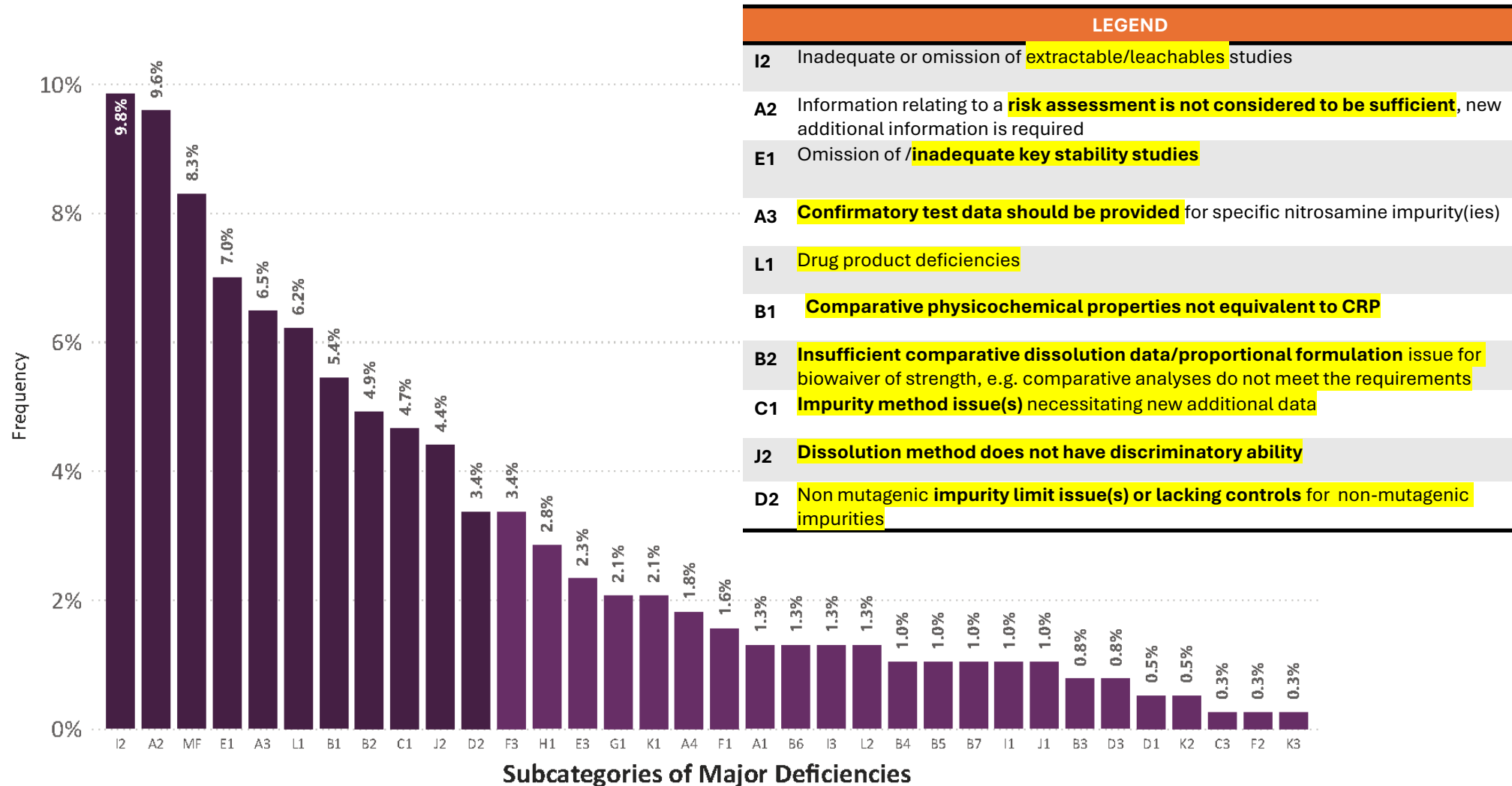
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Top Major Deficiencies for 2023-2024 FY



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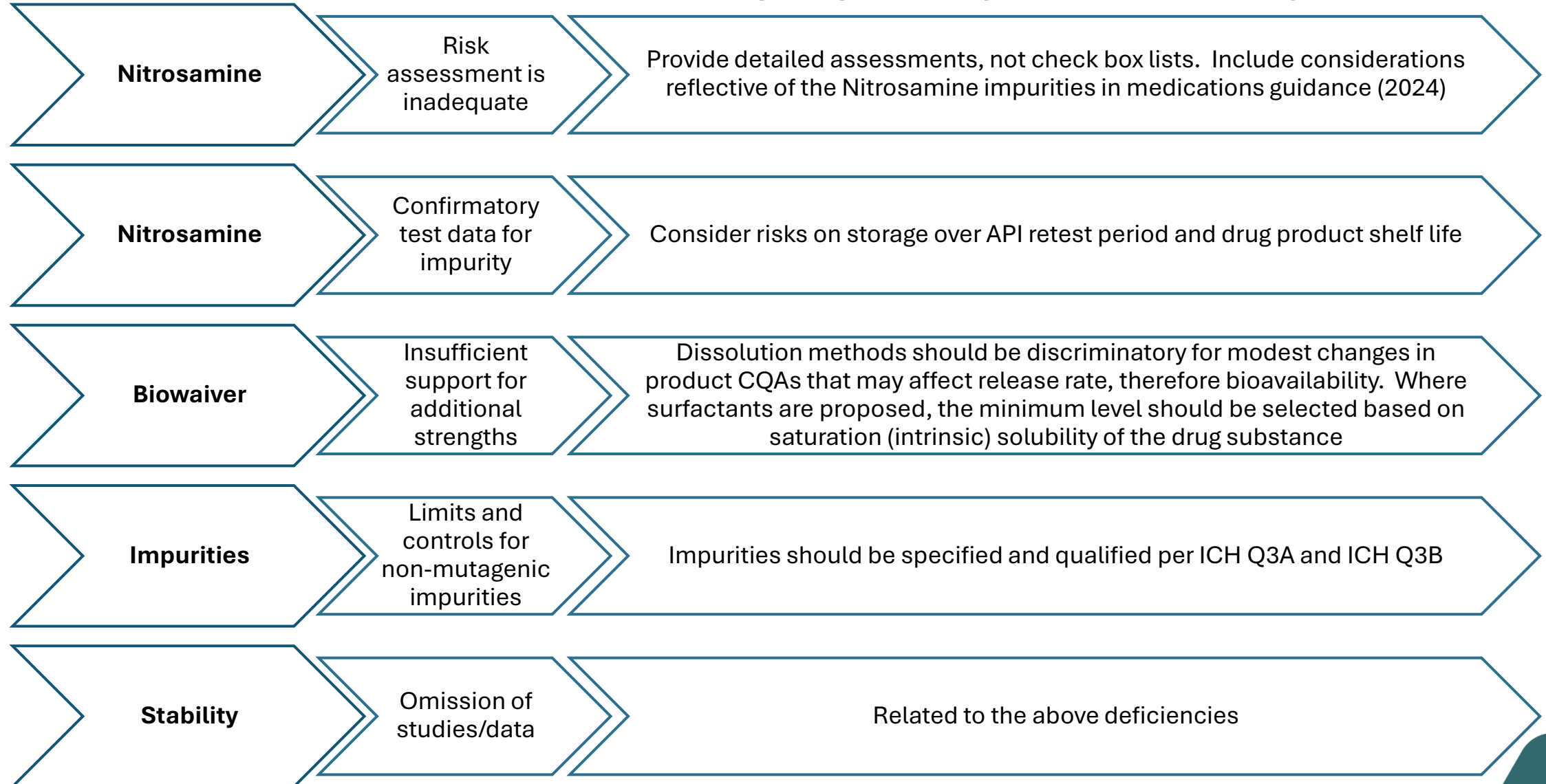
Top Major Deficiencies for 2024-2025 FY



*Received data is unaudited data

Negative Decisions

Tips to potentially avoid the deficiency



Key messages

- The common goal is to improve the positive decision rate in first cycle of reviews, as negative decisions are costly
- Approach to the issue of aligning expectations in dossiers
 - High quality submissions are essential to facilitate the timely review of drug submissions
 - Review recurring deficiencies and undertake measures to prevent in future submissions
- Understanding the reasons for negative decisions allows us to potentially help applicants bridge gaps

