



EDA & Stage Group Metrics: Can These Metrics Detect Product Changes?

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on behalf of the
IPAC-RS Cascade Impactor Working Group

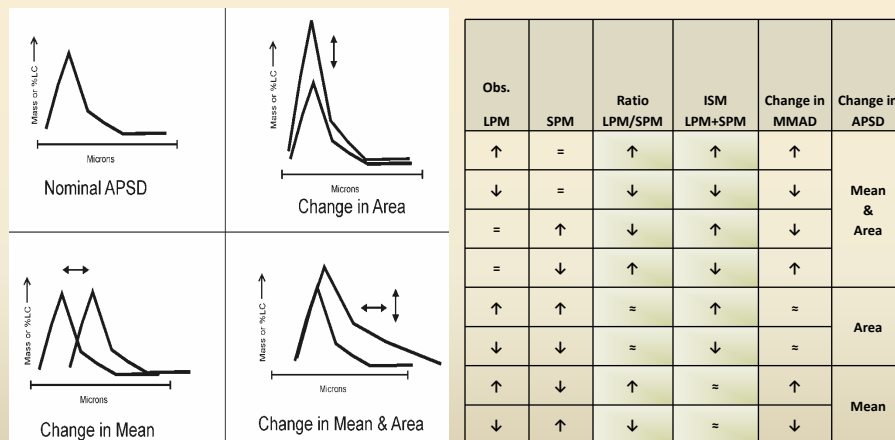
PERCHED & WAITING. SO ARE WE READY TO GO?



Objectives

- Present actual example data that “qualitatively” compares the EDA metrics calculated from 8-stage full resolution APSD by CI with the Stage Grouping and FPD Metrics.
- Identify relevant “quantitative” questions for future discussion and case study work.

APSD CHANGE and EDA Metric



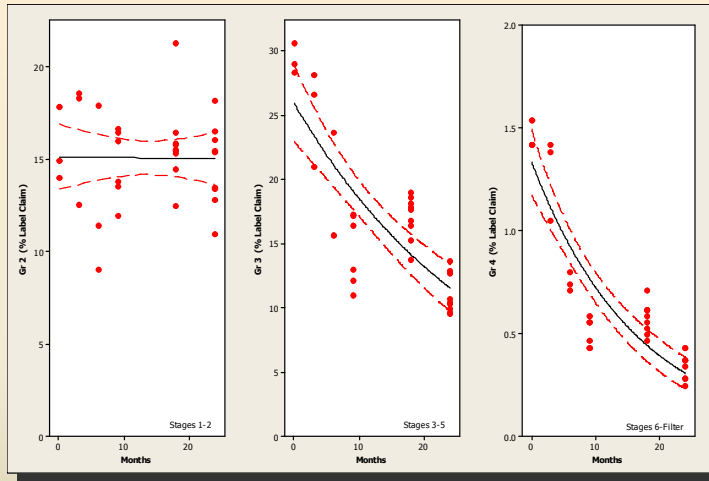
APSD CHANGE and Stage Groupings

- Stage Groupings can be used to predict changes in ISM.
- Predictions are not always as readily seen as with the EDA metrics.
- Relationship between a Stage Grouping and MMAD would need to very strong to be as predictive as Ratio and MMAD.

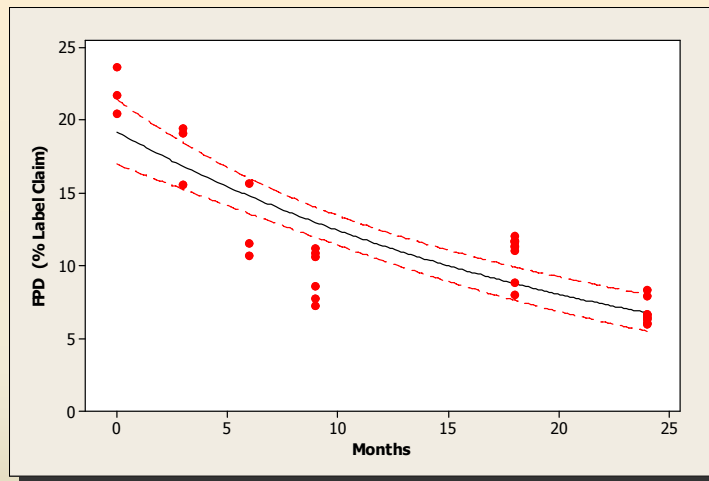
Case Study A and B Background Information

- Older product not currently on the market
- Real stability data that signaled a real issue
- Probable Cause Identified during Investigation

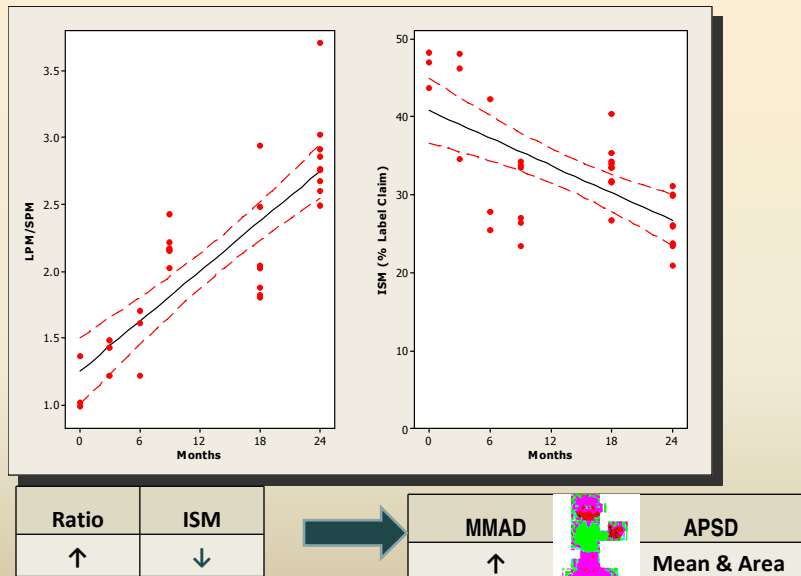
Case A: Stage Groupings



Case A: Fine Particle Dose



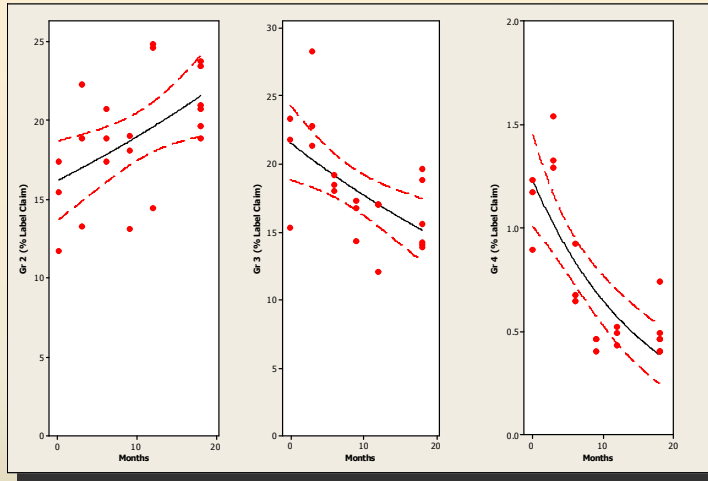
Case A: Efficient Data Analysis



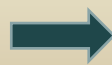
Case A: Observations

- Significant Stability Trend Indicated by
 - Stage Groupings (Group 3 and 4)
 - FPD
 - EDA
- Group 4 Stability Change for Batch
 - would not be identified as a specification risk
 - spec is typically one-sided upper limit.
- EDA Stability change corresponds to
 - increase in MMAD
 - decrease in ISM

Case B: Stage Groupings

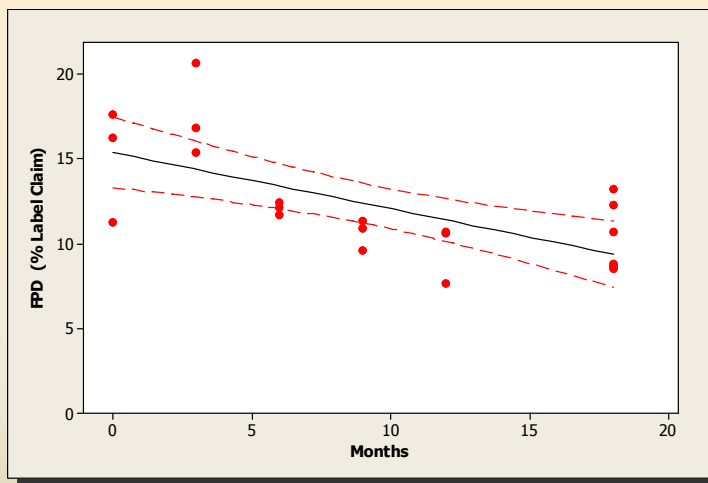


Group 2	Group 3	Group 4
↑	↓	↓



MMAD	APSD

Case B: Fine Particle Dose

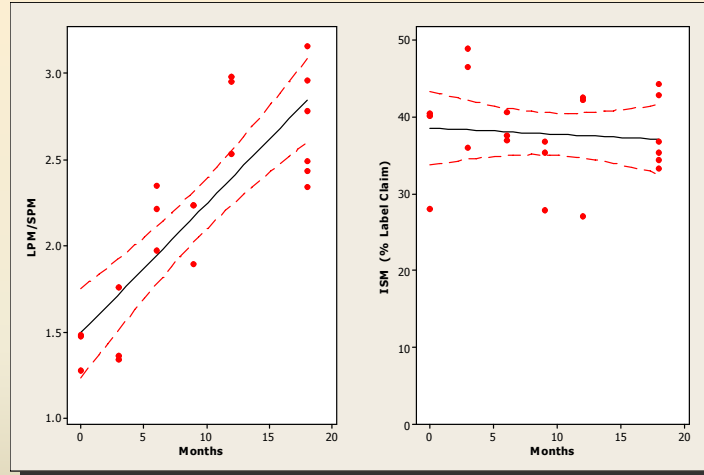


FPD
↓



MMAD	APSD

Case B: Efficient Data Analysis



Case B: Observations

- Significant Stability Trend Indicated by
 - Stage Groupings (Group 2, 3 and 4)
 - FPD
 - EDA
- Group 4 Stability Change for Batch
 - would not be identified as a specification risk
 - spec is typically one-sided upper limit.
- EDA Stability change corresponds to
 - increase in MMAD
 - no change in ISM

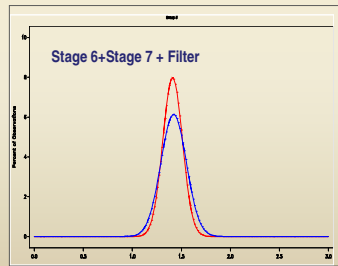
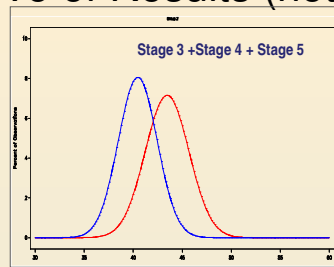
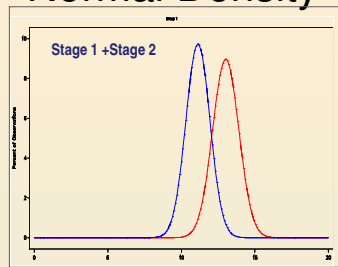
Case Study C

Background Information

- Deliberate product design change
- Observed subtle difference in APSD response

Case C: Stage Groupings

Normal Density Curve of Results (not APSD)



SS12	SS345	SS67F
↑	↑	=

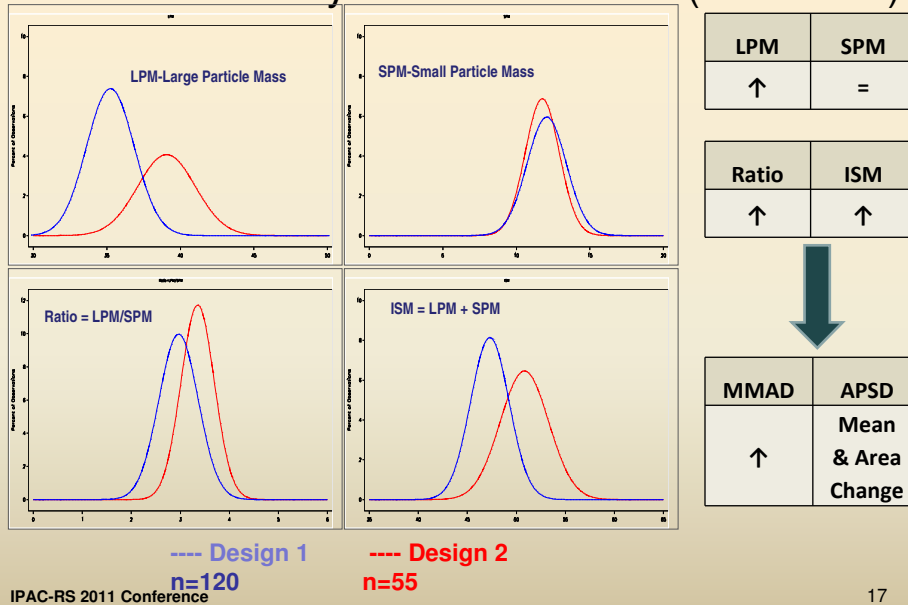


MMAD	APSD
12345	Force

---- Design 1
n=120

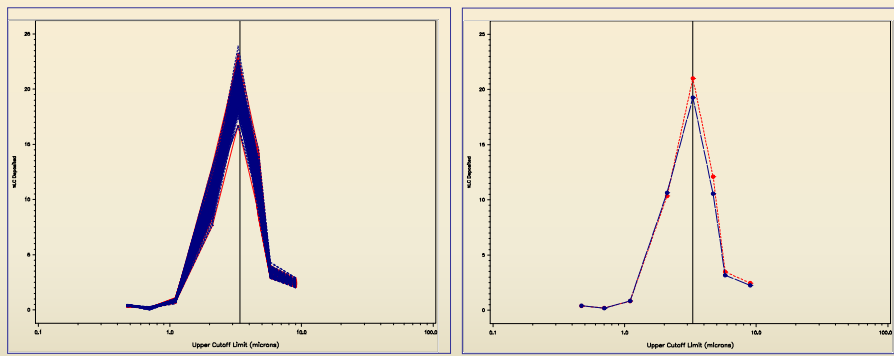
---- Design 2
n=55

Case C: EDA Normal Density Curve of Results (not APSD)



Case C: APSD by CI

Individual Profiles Mean Profiles



Future Case Study Questions

- What data analysis comparisons are required between the Stage Group Metrics and the EDA Metrics to Implement AIM/EDA approach on a Legacy Product?
- Decision Making Ability through Operating Characteristic Curves

LIP-SMACKING GOOD! WHAT ABOUT EDA?



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