

A journey from Exploratory to Regulatory Bioanalysis

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EBF 8th Open Meeting - Into New Territories - Explore, Learn and Apply

18-20 Nov 2015



A journey from Exploratory to Regulatory Bioanalysis

Introduction

Same Task - Different perspectives

Same Words – Different interpretation

Summary



My journey - Introduction

Scientific Background



AstraZeneca R&D Gothenburg site Sweden



Cathedral of Lund, Sweden



My journey - Introduction

Validated
method higher
LOQ?

RUO Is the
quality good
enough?

Is the result a true
response or due to
external factors?

Why
does GxP need
so much matrix?



Why
GxP so slow
turnaround
time?

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Same Task - Different perspectives

Analysis of Clinical study Biomarkers

- Exploratory – Discovery
 - Focus is Biology
 - The Biomarker
- Regulatory – GxP
 - Focus is Analytical Characteristics
 - The Method



Same Task - Different perspectives

Method Quality Control/Validation

- ROU - Research Use Only – Scientist determine characteristics of method
 - IUO - Investigational Use Only – Clinical trials – gather performance data
 - IVD - In vitro diagnostic - to detect , diagnose or monitor diseases.
-
- Different regulatory demands on kits
 - Intended use will guide your specific validation needs



Same Task - Different perspectives

Documentation

- Exploratory document to protect IP
- Regulatory to protect data integrity and People/Animal well being.



Same Task - Different perspectives

Checking data vs Data checking

Please
check my data
(Sanity check)



DATA CHECKING!
Formal procedure



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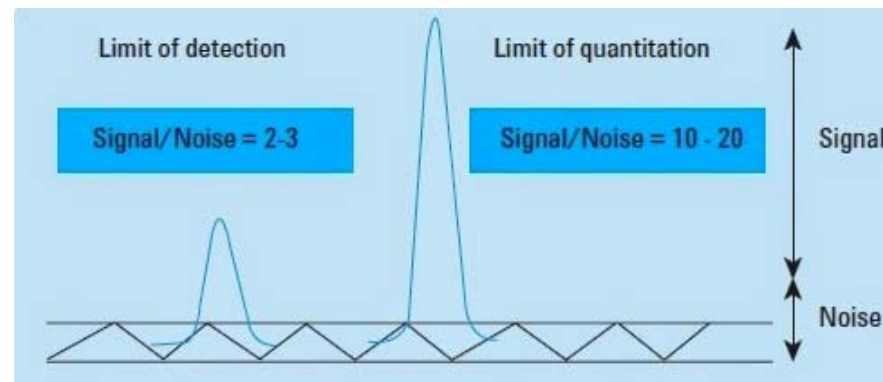
Summary



Same Words – Different interpretation/Definition

▪ LLOQ

- LOQ as defined by ICH –Lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy.



- LOD as defined by ICH –Lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.



Same Words – Different interpretation

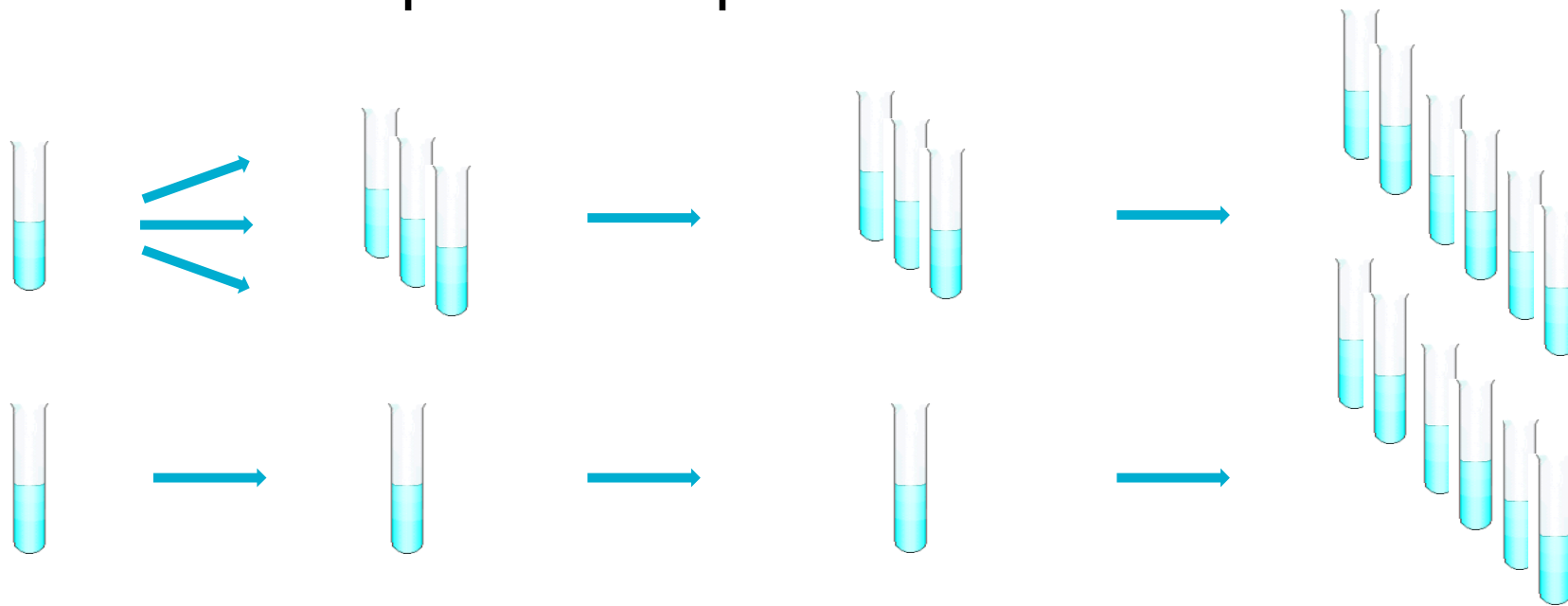
Robust Method

- Result = Relative difference between groups
 - OK if
 - Has a signal in range
 - Good shaped standard
 - Good intra batch Precision
- Same sample = Same result
 - Regardless of:
 - analyst
 - Time
 - Geography



Same Words – Different interpretation

Precision – Aliquot vs Replicates



Mother
sample

Aliquot

pre-analytical
steps

Assay
duplicates



Same Words – Different interpretation

Fit for purpose

- Intended use
- What question is to be answered by the method



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My journey - Conclusions

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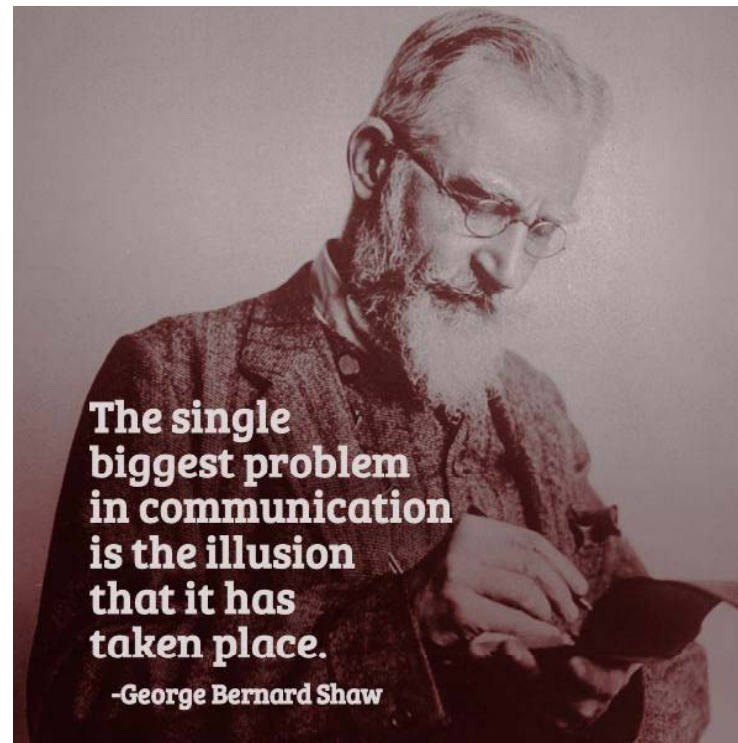


Why
GxP so slow
turnaround time?



IT ALL COME DOWN TO IS

Communication!



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Back up slides