



MMQCI'S FDA EXPERIENCE

EuroGentest Symposium on Reference
Materials for Genetic Testing

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WHY

- High quality product for healthcare
- Regulations
- Competitive advantage
- We like pain

WHAT

- QSR → cGMP
 - 21 CFR Part 820
- ISO 13485
- Validation, verification, etc.
- Clinical trials

HOW

- **Guidances**
 - Preparation of 510(k) Submissions FDA 97- 4224
 - Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material
 - Class II Special Controls Guidance Document: QC Material for CF Nucleic Acid Assays
- **Consultants**
- **Talk to the FDA**
- **Test, test, test**
- **Document, document, document**

WHAT ELSE

SUBMISSION

- Format
- Manufacturing summary
- Accuracy determination
- Stability studies
 - Accelerated, Real time, Open vial, Stress
- Clinical evaluations: 3 lots
- Matrix effects
- Protocols and labeling

WHAT WAS IT LIKE?

- Scary

- What if they ask us to do testing we can't afford?
- What if they tell us we can't sell the product?

- Expensive

- \$3,066 is a lot for a small company
- Molecular testing is expensive

- Time-consuming

- Become familiar with rules
- Write the submission
- Perform more testing and re-write submission

BUT.....

- FDA was helpful
- Thorough testing increases quality
- QSR/ ISO are needed for quality products
- FDA listened
- INTROL™ CF Panel I was CLEARED!!
- Next one will be easier (?)