FDA ACPS PAT SUBCOMMITTEE

CHALLENGES OF PAT SYSTEM IMPLEMENTATION

IN THE AREAS OF

***COMPLIANCE - COMPUTER SYSTEM VALIDATION**
- Reg 21 CFR 11

***C GMP - A RISK – BASED APPROACH TO QUALITY MANAGEMENT**

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PAT SUBCOMMITTEE MEETING 23/10/02

CONTENTS

1. THE 3 LEVELS OF PAT SYSTEMS

(a) The stand-alone application
e.g NIR Analyser and PC – Material Classification.

(b) The total Facility RTQC/RTQA ethernet approach.

(c) The upper Level IT Compliant System for:-

- **Large volume diverse data storage management and modelling Functionalities.**
- **The Manufacturing Execution System.**

2. Validation and 2ICFR11 Considerations For Levels 1 and 2 – The General Solid Dosage Facility.

* **List of Computer System Validation Documents.**

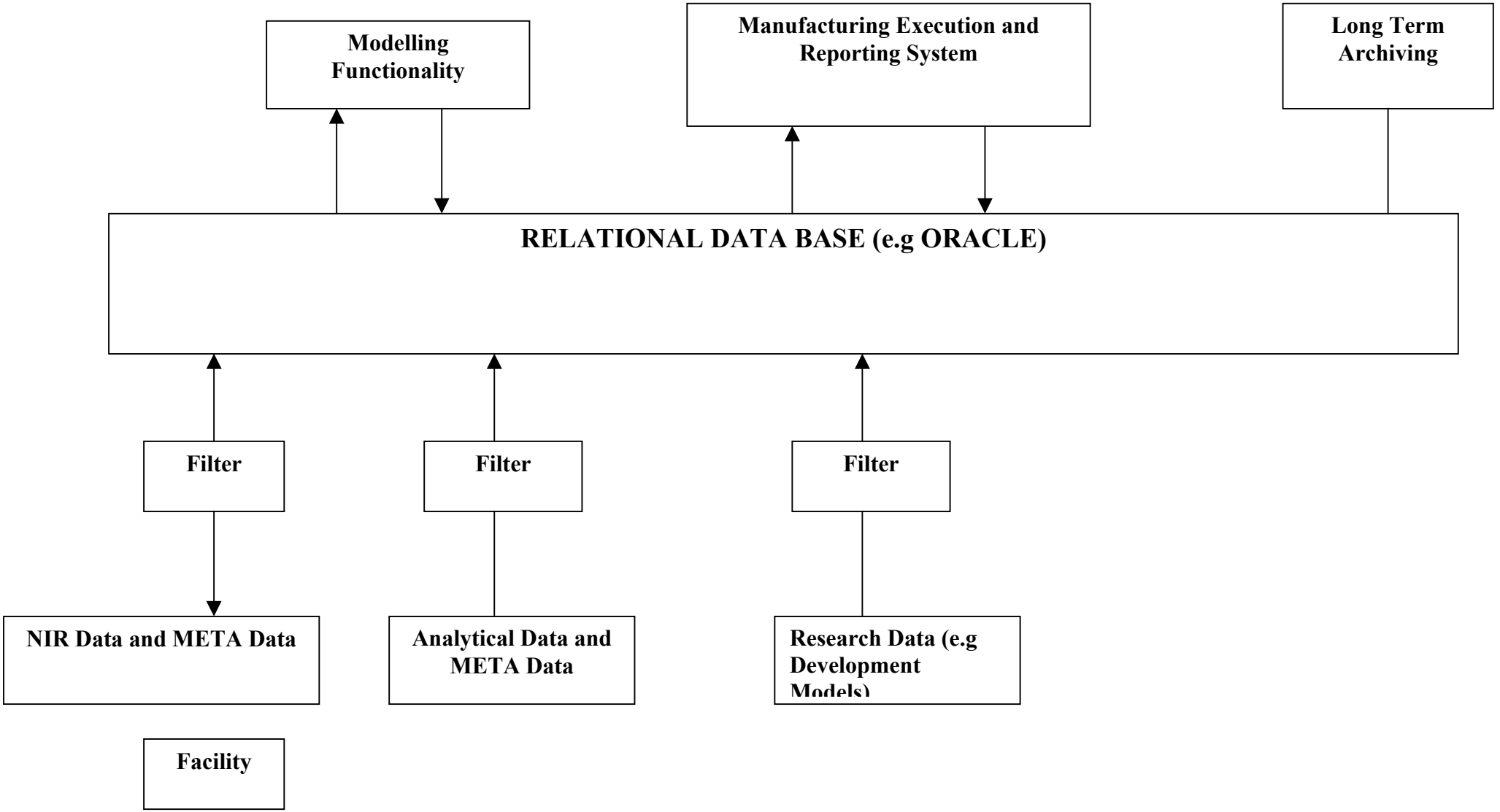
* **21CFR11 Considerations** - **Strategy Document**

  - **As an inherent component of CSV Test Documentation.**

* **Risk – Based Approach** - **FMEA, Password Hierarchy, Windows 2000 IT security, Audit Trail Philosophy.**

* **Data transfer protocols.**

3. **SCHEMATIC** - **Functionalities required of the Level 3 Compliant IT System for PAT Implementation.**



***Data Format Considerations, Software Filters, and 21CFR11 Storage and Data Manipulation.**

***The Model Stage.**

***Model Validation.**

***Model Approval and Revision Hierarchies.**

***Manufacturing – Criteria for the Release Decision.**

***Compliance – Requirements of the Regulatory Bodies.**

***Archiving – Requirements of the Regulatory Bodies.**

***Development Data and Models.**

4. Manufacturing Execution System Functionalities.

***Real Time Batch Statistical Monitoring.**

***Historical Trending including Current Batch Parameters.**

***Statistical Distribution Compilation for Key Quality Parameters in the sample population.**

***Inherently a methodology to understand and manage manufacturing processes effectively**.

C GMP - MES System Potential to Manage the Risk

***Ultimately Risk is a statistical evaluation.**

***MES systems provide distributions of (e.g) Tablet Parameters statistically sampled throughout the batch.**

***Analysis of normal distributions evaluates the risk.**

***Statistical monitoring and control manages the risk.**