can stand the stringent requirements of Pharmaceutical Manufacturing

- Sakthivel Vellingiri
OFBiz & Pharma Manufacturing

• OFBiz
  – Great general purpose ERP platform
  – Backed by solid framework
  – Robust tools for extension
  – Universal data-model

• Pharma Manufacturing
  – Highly regulated
  – Constantly changing regulations
  – Highly values Intellectual property
Challenges in Pharma Manufacturing

• Approval workflows
• Inventory Management for limited shelf life items
• Traceability
• Auditing
• Multi-Level Formulation
• UoM conversion
• Regulatory compliance
Approval Workflows

- Dashboard approval
- Email notification
- Modularized & Integrated
- SSO across different modules
Inventory Management for limited shelf life items

• Expiry date for Inventory Items
  – Procured & Manufactured

• Track by status

• Lot number
  – Auto-generated for Procured & Manufactured

• Inventory Location

• Inventory Transfer
Traceability

- Expiry date for Inventory Items
  - Procured & Manufactured
- Track by status
- Lot number / Batch number
  - Procured & Manufactured
- Inventory Location
  - Manage own locations
- Inventory Transfer
- Track Variances
  - e.g. Analytical & QA Sample
- Inventory Item Label
Auditing

• Event driven Audit Trials using Event Condition Action (ECA)
• Auditing of Inventory receipt thru production
• Auditing of Batch Manufacturing records
• Auditing of formula changes & workflow approval
• Tracks workflow approval & effective dates in history logs
UoM Conversion

• UoM conversion to support batch process
• Automatic UoM conversion during formulation
Multi-level Formulation

- Formula specification of intermediates & products
- Multi-level formula specification
- Embedded special manufacturing instructions
- Mix & Match Formula & Products
- Formula approval workflow
- Formula version control
- Support for user defined physical characteristics
- Supports products with different strengths & physical characters
  - Using Virtual & Variants
Regulatory Compliance

• Version control in history log
• Bi-directional lot traceability
  – Tracks inventory items of ingredients used in batch
• Tracks Intermediate or WIP items
• Support for discarding un-used items
• Managing formula revisions
• Document management e.g. Certificate of Analysis
• Recall Management using bi-directional traceability
Q & A