can stand the stringent requirements of Pharmaceutical Manufacturing

- Sakthivel Vellingiri

Integrin
Enterprise Solutions

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

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Challenges in Pharma Manufacturing

- Approval workflows
- Inventory Management for limited shelf life items
- Traceability
- Auditing
- Multi-Level Formulation
- UoM conversion
- Regulatory compliance
- Open Source Myth
- Role based access control

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Approval Workflows

- Dashboard approval
- Email notification
- Modularized & Integrated
- SSO across different modules

Applications | Dashboard for :

My Open Material Requests

Material Request	Date
Material Request [10071]	9/23/14
Material Request [10071]	9/23/14
Material Request [10071]	9/23/14
Material Request [10161]	12/23/14
Material Request [10161]	12/23/14
Material Request [10161]	12/23/14

My Completed Material Requests

Material Request	Date
Material Request [10040]	9/16/14
Material Request [10040]	9/16/14
Material Request [10040]	9/16/14

Incoming Material Requests

Page 1 | 20 Items per page | Displaying 1 - 20 of 71

Material Request	Date
Material Request [10161]	12/23/14
Material Request [10160]	12/23/14
Material Request [10152]	11/4/14
Material Request [10151]	11/4/14
Material Request [10150]	11/4/14
Material Request [10143]	10/1/14
Material Request [10142]	10/1/14
Material Request [10141]	10/1/14
Material Request [10140]	10/1/14
Material Request [10139]	10/1/14
	10/1/14

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

Edit Inventory Item

[redacted]

Inventory Item Id	10126 *This cannot be changed without re-creating the inventoryItem*
Product Id	10172
Supplier	
Status	
Date Time Received	1/4/2015 1:34:11 AM
Expire Date	
Warehouse Id	[redacted]
Container Id	
Batch Number	0104Demo1
Inventory Location	
Comments	Created by production run 10343
Available To Promise / Quantity On Hand	0 / 0

Update

Physical Inventory Variances

Component Inventory

Inventory Item Id	Component Id
10051	10174

Product Inventory

Inventory Item Id	Product Id
10127	10170

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

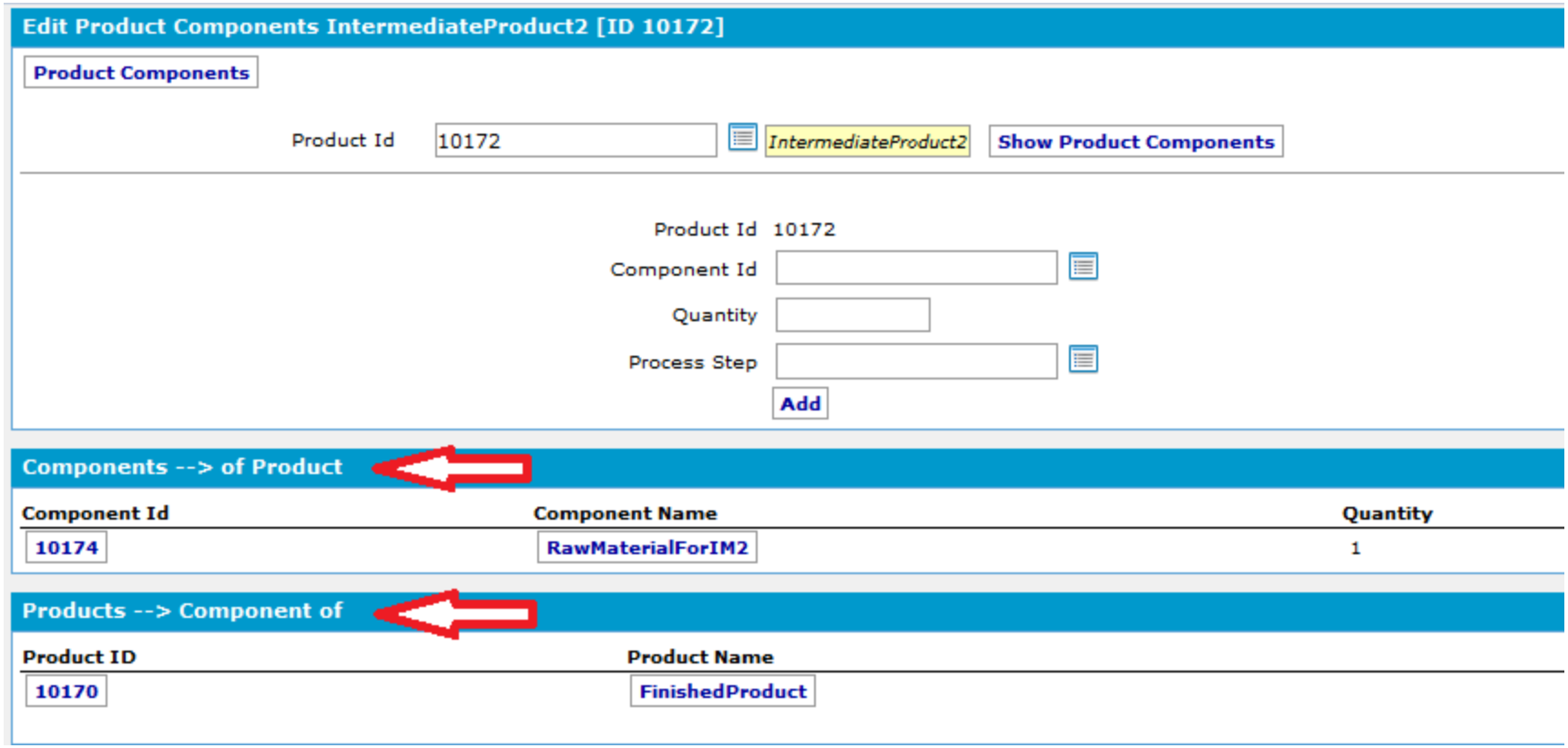
- Event driven Audit Trials using Event Condition Action (ECA)
- Auditing of Inventory receipt thru production
- Auditing of Batch Manufacturing records
- Auditing of formula changes & workflow approval
- Tracks workflow approval & effective dates in history logs

UoM Conversion

- UoM conversion to support batch process
- Automatic UoM conversion during formulation

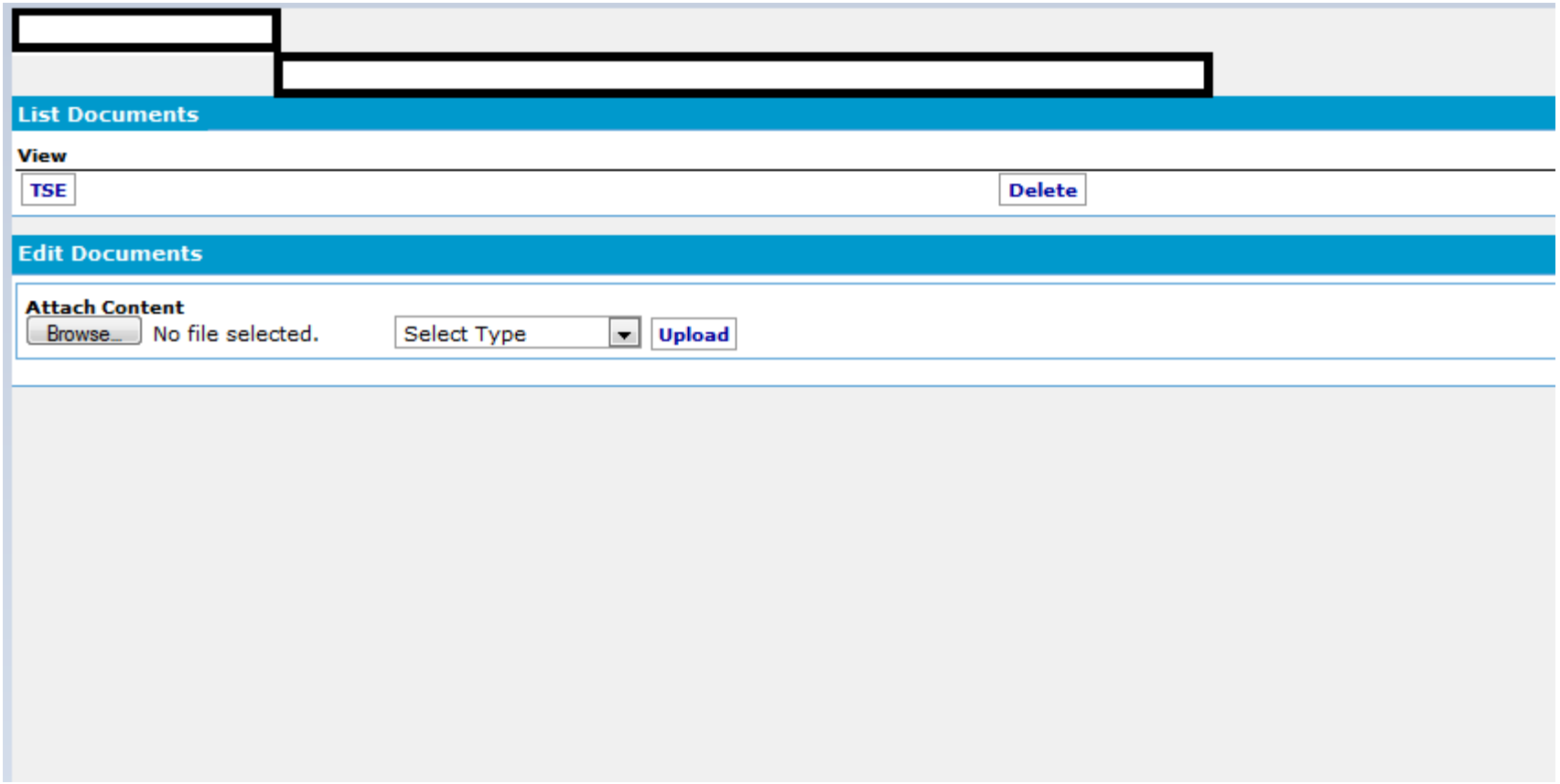
Multi-level Formulation

- 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



Next Steps

- FDA Filing
- Identify Niche

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Q & A