

freyr®



CASE STUDY



SUCCESSFUL  
**LABEL TRACKING**

& **DATA MIGRATION**

[www.freyrlabel.com](http://www.freyrlabel.com)



## PROJECT IN SCOPE & BUSINESS IMPERATIVES

- ❑ Large Global Pharmaceutical Company
- ❑ Label Tracking and Data Management for Multiple Product Categories/Portfolios and 50,000+ Tracking Records and Additional Downstream System Datasets
- ❑ Transformation and Migration of Change Control, Labeling, Artwork and Supply Chain Systems from Multiple Sources to a Single Tracking System
- ❑ Ensuring Smooth Cutover and Process Transition as per Compliance Standards



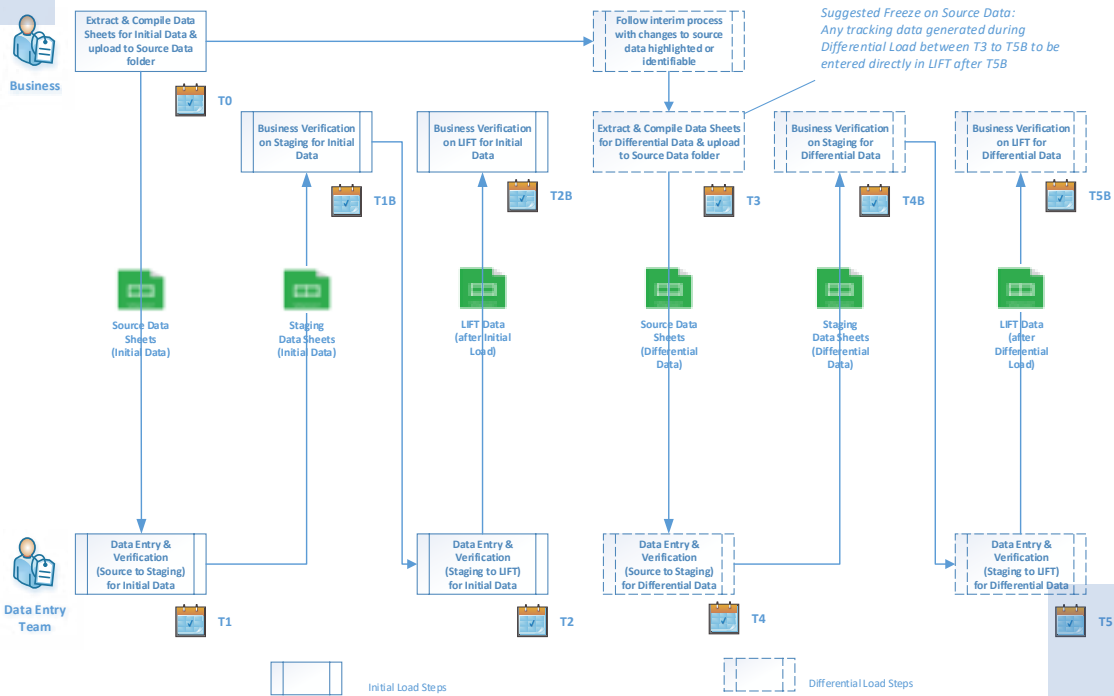
## FREYR'S SOLUTIONS AND SERVICES

- ❑ Multiple Data Movement Strategies (Portfolio/ Source/ Scope/ Complexity)
- ❑ Migration Requirements & Plans
- ❑ Mapping & Rule Books
- ❑ Work Instructions, Templates
- ❑ Protocols, Scripts, Checklists
- ❑ Summary Reports



### Multi-complexity Data Workstreams

#### Data Entry Cycle – 1 Initial Data Load & 1 Differential (Delta) Load



### Movement Strategies and Processes

SP-Code Description Code	Change Description	Is Import	Origin Country	SP- Market Status	SP-Product Description	Tracking Sheet Name	Tracking Column Name	Reason Code	Reason Description	Business Rule Name	Business Rule Description	Business Rule Status	Business Rule Priority
US-000	SP-Change	Yes		NA	This SP-Code is currently approved to identify certain US-000 products from US-000 facilities. It is intended to identify US-000 products for which a separate US-000 code is required.	Request	US-000	US-000	Consolidated Sheet	US-000 (US-000) is a US-000 product. It is intended to identify US-000 products for which a separate US-000 code is required.	Yes		US-000 (US-000) is a US-000 product. It is intended to identify US-000 products for which a separate US-000 code is required.
US-000	SP-Change	No	US	SP-Request Status	Origin	Request	Origin	US-000	Consolidated Sheet			Yes	
US-000	SP-Change	No	US	SP-Request Status	Product	Request	Product	US-000	Consolidated Sheet	US-000 (US-000) is a US-000 product. It is intended to identify US-000 products for which a separate US-000 code is required.	Yes		
US-000	SP-Change	No	US	SP-Request Status	Other Imported Product								
US-000	SP-Change	Yes	US	SP-Request Status	Request Item	Request	Request Item	SP-000				Yes	

## Mapping and Rule Books

Take the reason from column "Reason for non-submission" of SP-Impact Assessment sheet

Enter in column "Reason(s): If "No Submission/Notification Required"" of Tracking sheet

Sheet/Column in COMPLIANCE TRACKER- ACTELION	Sheet/Column in LIFT Actelion Staging Data Sheet
SP-Impact Assessment / Reason for non-submission	Tracking / Reason(s): If "No Submission/Notification Required"

### 1.1.1.1. Entering data regarding dependency under Country Administration

#### a) Entering Brief Change/Save Reason Description Text

Please refer LIFT Actelion Data Entry Rule Book for the associated business rule.

#### b) Entering Tracking Path

Please refer LIFT Actelion Data Entry Rule Book for the associated business rule.

#### c) Entering Start Tracking Date

Please refer LIFT Actelion Data Entry Rule Book for the associated business rule.

#### d) Entering Final Tracking Date

Please refer LIFT Actelion Data Entry Rule Book for the associated business rule.

#### e) Entering Dependent On Milestone/Tracking Date

Take the dependent milestone from column "Dependent On Milestone/Tracking Date" of SP-Reference Countries Sheet.

Enter it in column "Dependent On Milestone/Tracking Date" of Tracking sheet.

## Work Instructions



# DATA COLLECTION

- Milestones completion, compliance
- Quantitative Summaries
- Data Quality Dashboards



## Quantitative Summaries

Source	Project	Data	Records	Resolving	New	Handling	Open	Work	Quality	Total	To be	In Scope	Records	Records	Records	Records	Records	Records
			No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of	No. of
Pharma	As-Track-CCDS-Global	Global CCDS Changes	88	78	173	276	312											
Pharma	As-Track-CCDS-Global	Country level data	4712	3230	6775	34038	340	11465										
Pharma	As-SPS-CCDS-All	SPS-CCDS Global (non migrated)		284	154													
Pharma	As-SPS-CCDS-All	SPS country level (non migrated)		18978	10976													
Pharma	As-Track-local	Locally initiated changes (MCP only)		66														
Pharma	As-Track-local	Locally initiated changes (MCP only)		4706														
Pharma	As-Data-CCDS-Global	Day E to F02 Backlog		213		204	416											
Pharma	As-Data-SUP-All	ISS data		40														
Consumer	Co-CCDS-Global	Global CCDS Changes	64	111	262	390	218	391										
Consumer	Co-CCDS-Global	Country level data	2897	1094	6046	11240	2302	6757										
Consumer	Co-Consumer-All	Consumer Mgmt data	40															
Consumer	Co-Data-SUP-All	ISS data	40															
Actelion	As-CCDS-Global	Global CCDS Changes (only CCP updates)	38	6		10	7	28										
Actelion	As-CCDS-local	Country/Invoice level data (only CCP updates)	471	373		1178	345	961										

## Qualitative Dashboards



# STAGING AND VALIDATION

- ▢ Staging Data Sheets (manual)
- ▢ Data Import Logs (automated)
- ▢ Validation Checklists

S. No.	Item Description	Yes	No	Issues found/ Comments
<b>A Staging Data Sheet: Request</b>				
1.	Origin verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Request Topic verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Request Description verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
4.	Priority verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Day 0/Decision to start note verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
6.	CCDS LC Sign Off note verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
7.	Target Submission Date note verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
8.	Target Submission Date Timeline Extension note verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
9.	Target Submission Date Timeline Extension reason verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
10.	Legacy Tracking Number verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Request Sheet verified with no issues?</b>		<input type="checkbox"/>	<input type="checkbox"/>	
<b>B Staging Data Sheet: Request Text</b>				
1.	Request Text ID verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Request Text verified as per business rule?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Request Text Sheet verified with no issues?</b>		<input type="checkbox"/>	<input type="checkbox"/>	

Validation/Quality Checklists



# MIGRATION AND QC

Migration Logs & Summary Reports

QC Reports & Analysis

Phase	Migration Input File #	Round	Start Date/End Date/executed by/ verified by	Migration Results	Re-run	1% Sample Verification post run
1	Pharma_Global_Changes_2015-16.xlsx	1	Start Date:29-Sep-2017 End Date:29-Sep-2017. Executed By: Kishore Kumar.H Verified By : Kamalteja Konidena Verification Start Date:29-Sep-2017 Verification End date:29-Sep-2017	Completed; with 0 errors(s)	NA	Sample Size:32 Passed: 32 Failed:0

Migration Summary Reports



# CLIENT BENEFITS

50,000+ Tracking Records

Qualitative Summaries

Periodical Validation and Quality Checklists

A Single-stop Comprehensive Tracking System

Smooth Transition and Compliance

# About Freyr

Freyr is one of the largest, global, Regulatory-focused solutions and services companies for the Life Sciences industry, supporting Large, Medium, and Small size global Life Sciences companies (Pharmaceutical | Generics | Medical Device | Biotechnology | Biosimilar | Consumer Healthcare: Cosmetics | Food Supplements | Chemicals) in their entire Regulatory value-chain, ranging from Regulatory Strategy, Intelligence, Dossiers, Submissions, etc. to Post-approval/Legacy Product Maintenance, Labeling, Artwork Change Management, and other related functions. Freyr is also expanding its footprints into other key areas like Pharmacovigilance.



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