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WHITE PAPER

A Novel Power BI Tool to Monitor Change Controls and Key Performance Indicators

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Abstract

A novel Change Control Monitoring Dashboard using the Power BI Tool was developed to provide real-time Change Control status in multiple regions viz. Asia pacific (APAC), Europe/Middle east (EMEA), and Latin American (LATAM) markets periodically (weekly, monthly, quarterly, or annually). The tool extracts necessary information from Change Control data reports.

The Power BI tool enables managers and executives to track change control status, identify bottlenecks for completion, and prioritize regulatory submissions across global regions. The tool may also be used for real-time tracking of metrics parameters such as key performance indicators (KPI).

Introduction

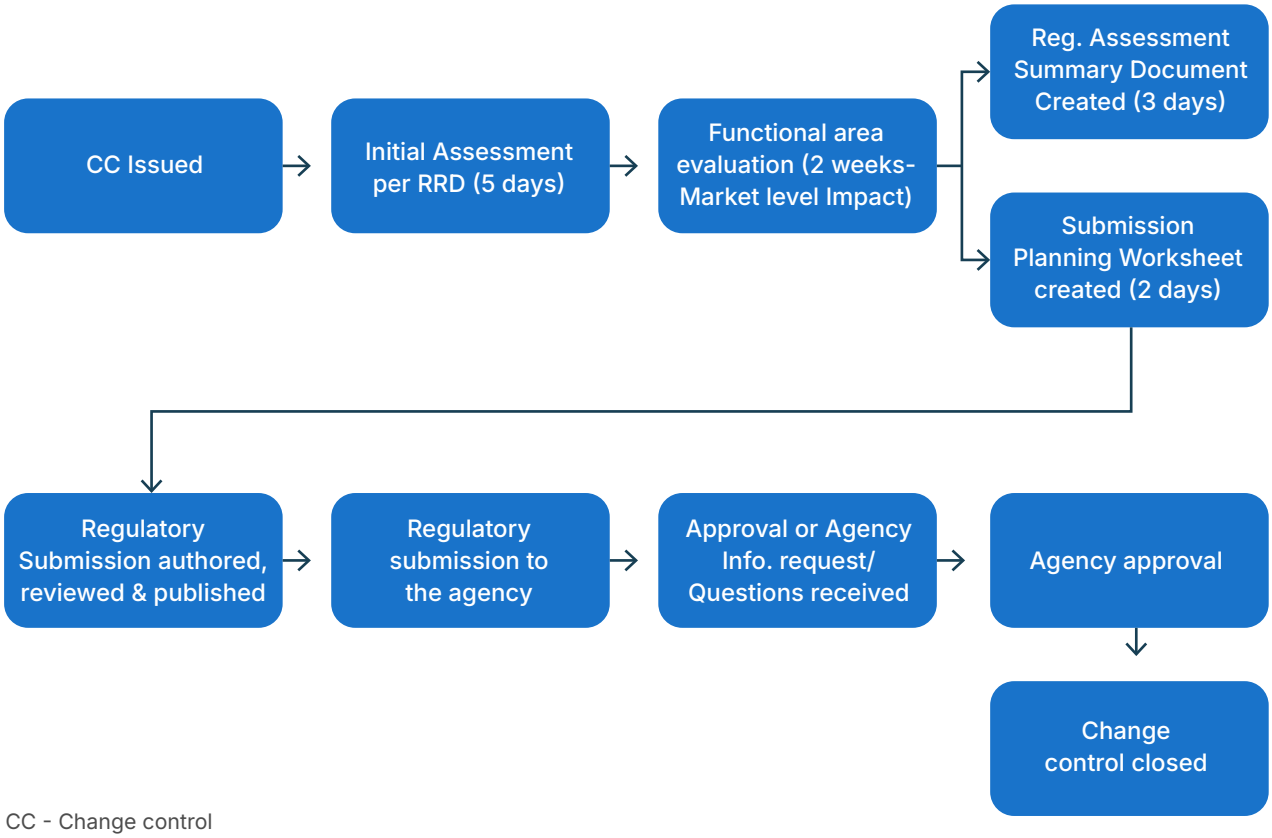
One of the essential pillars of the good manufacturing practices (cGMPs) in Pharmaceutical / Biotech industry is effective management of Change Control and related systems. The regulatory agencies worldwide (FDA, EMA, PMDA, NMPA, and other major agencies) during site inspections examine the Change Control system at a firm to assess compliance with the cGMP standards and regulatory requirements. It is necessary to report and seek regulatory agency's approval for changes in the drug substance (DS) or drug product (DP) components and composition, manufacturing processes, manufacturing sites, specifications, reference standards, analytical procedures, packaging, or stability profile to ensure and demonstrate a state of compliance.

As a result of Change Control evaluation, the changes to DS, DP, excipients or manufacturing systems are reported to the agencies via prior approval supplements (PAS)/Variations or Annual reports/ Renewals to seek its approval.

Change Control Life Cycle

The Change Control life cycle consists of multiple stage gates such as initiation, technical, and regulatory impact assessment by functional areas, change execution and reporting to the agencies worldwide via appropriate regulatory mechanisms. Each change control stage gate from initiation to execution is tied to pre-defined timelines as per company policies and related SOPs. Typically, the Change Control are managed via dedicated systems such as Trackwise or ETQ as 100s of Change Control are issued in a calendar year which need to be evaluated for up to 150+ or more markets worldwide, depending upon the product registrations or intended supply. The change control impact assessment needs to be progressed in a timely manner so that the manufacturing, quality control, and product release functions stay current and in compliance with the regulatory requirements and cGMPs. Figure 1 below shows a flow chart for typical change control life cycle.

Figure 1. Flow chart of the change control stage gates, timelines, and submission process



CC - Change control

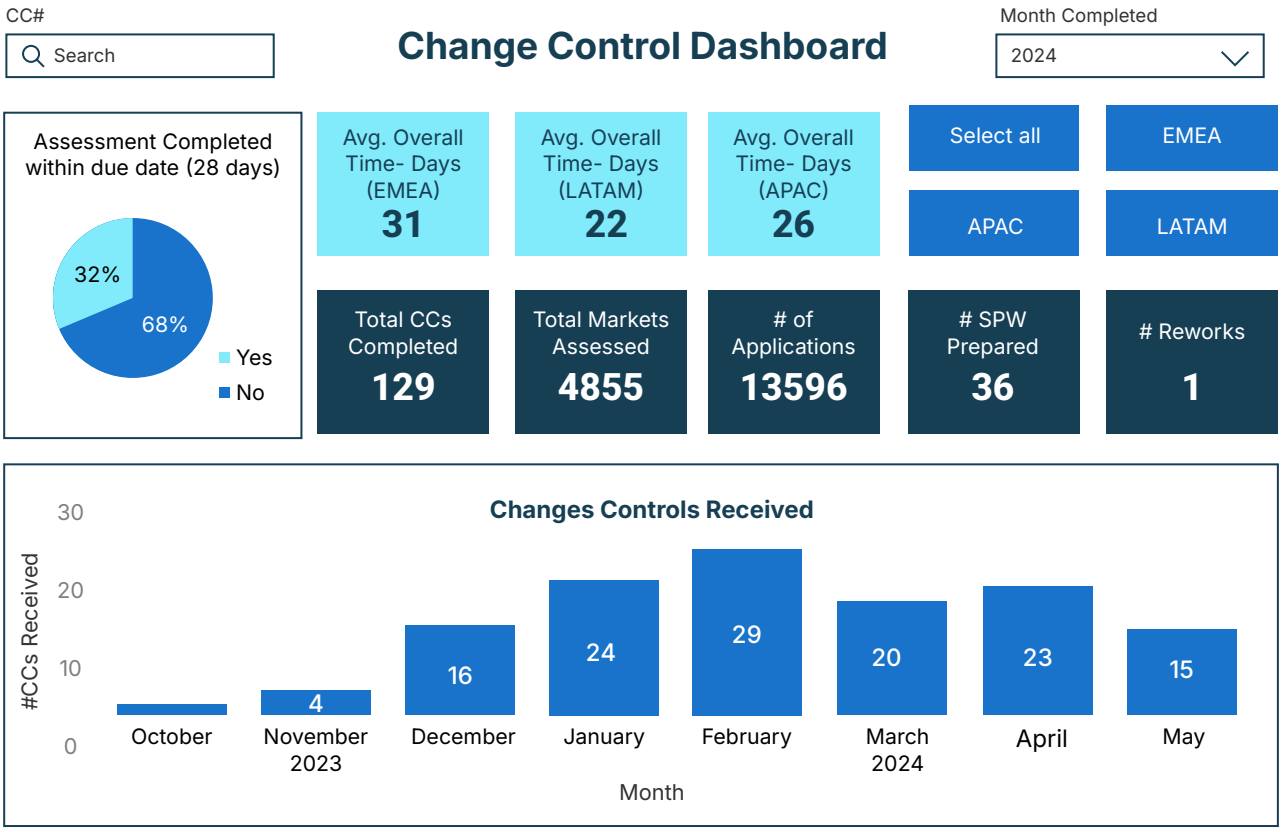
RRD - Regulatory Requirements Database

Power BI Tool

A tool has been developed using the Power BI that enables real-time tracking of Change Control status across multiple regions- APAC, EMEA, LATAM and for different time durations- weekly, monthly, quarterly, or a specified time duration. Figure 2 shows an example of a Power BI dashboard that exhibits information such as percentage of Change Control completed within certain no. of days (designated time per SOP) or percentage of outliers, average time taken for completing assessments in each region or globally (LATAM, EMEA, APAC), total Change Control completed, total number of markets, applications assessed, number of summary worksheets prepared, number of Change Control re-assessed for various reasons etc.. The dashboard also shows monthly Change Control evaluated in the past several months.

In an industry where hundreds of Change Control are initiated annually that may impact 150+ market registrations and product supply the real time monitoring of Change Control via such dashboards become very helpful in prioritization, quicker decision making, and ensuring continued product supply in the intended markets.

Figure 2. Change Control Dashboard



APAC- Asia Pacific countries

EMEA- Europe, Middle East countries

LATAM- Latin American countries

Key Performance Indicators (KPI) Monitoring

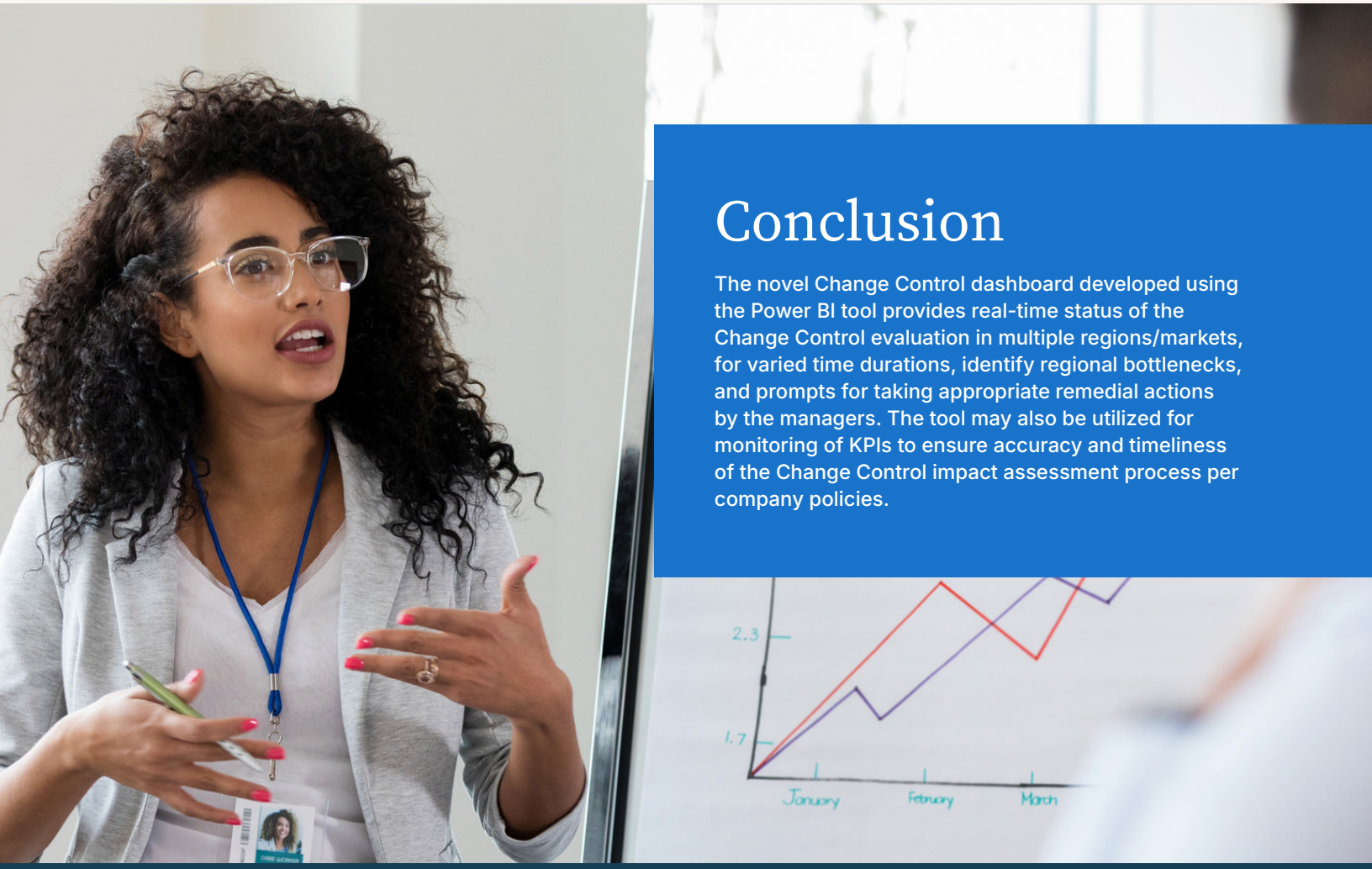
Additionally, the Power BI tool can also be utilized to develop a separate dashboard as above for monitoring the key performance indicators (KPIs) related to Change Control evaluation. As an example, Table 1 summarizes KPIs that can be identified in the Change Control evaluation process. The raw data collected for Change Control from the date of initiation to the completion of CCs evaluation are utilized to generate KPIs provided in Table 1 below over a period of 3 months. The duration of KPIs may be set monthly, quarterly, or yearly, as suitable.

Table 1. KPIs monitored for change control evaluations during the specified period (Quarter of the year)

KPI Description	APAC	LATAM	EMEA	Total/Average
No. of CCs initiated for evaluation in each region	43	44	41	128
No. of CCs crossed initial evaluation time (6 days)	10	20	10	13.3
No. of CCs completed final evaluation within specified no. of days (e.g. 30 days)	32	30	25	87
Percent CCs completed final evaluation within specified no. of days (e.g. 30 days)	74.4%	68.1%	60.9%	67.9%
No. of regulatory impact summary worksheets prepared (bundling of submissions)	10	10	13	33
RRD Codes identified correctly	90%	100%	90%	93%
Gap analysis (current and proposed CTD sections identified accurately)	100%	90%	90%	93%
Supporting/Reference documents identified correctly	90%	90%	90%	90%
Rework/Re-assessment of CCs required (%)	10%	10%	10%	12.8%

CC - Change control

RRD-Regulatory requirements database



Conclusion

The novel Change Control dashboard developed using the Power BI tool provides real-time status of the Change Control evaluation in multiple regions/markets, for varied time durations, identify regional bottlenecks, and prompts for taking appropriate remedial actions by the managers. The tool may also be utilized for monitoring of KPIs to ensure accuracy and timeliness of the Change Control impact assessment process per company policies.

ABOUT

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