TECHNOLOGY & BUSINESS SOLUTIONS

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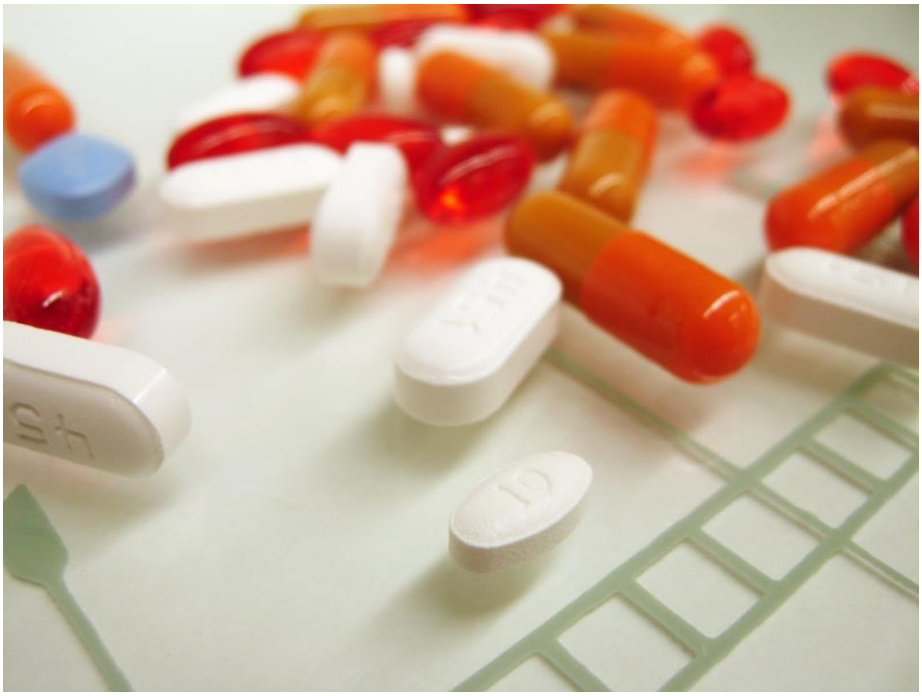
Pharmaceutical Manufacturing

Enhancing Quality and Good Manufacturing Practices (GMP) by Leveraging Technology and Software

White Paper



Developed by Technology and Business Solutions (TBS)

Enhancing Quality and Good Manufacturing Practices (GMP) by Leveraging Technology and Software

Industry Background

In Bangladesh the pharmaceutical manufacturing sector has more or less 250 licensed manufacturers. According to IMS, a US based market research firm the retail market size is estimated to be BDT 85 billion. The pharmaceutical sector is technologically the most developed manufacturing industry in Bangladesh and the third largest industry in terms of contributing to government revenue,

Bangladesh manufacturers 450 generic drugs for 5300 registered brands which have 8300 different forms of dosage and strength. Domestic manufacturers account for 97% of the drug sale in the local market while the remaining 3% are imported.

Bangladesh's overall export earning from Pharama products was around USD 46 million in 2011 and recorded an average growth rate of 15 % annually for the last seven years and is projected to have a similar growth rate in the future depending on overall global outlook.

As the domestic market becomes steady and saturated it is expected that future growth in this sector will mainly come from the export market.

Good Manufacturing Process (GMP/cGMP)

Good Manufacturing Practices (GMP) refers to an organization's ability to ensure that products are consistently produced and controlled to appropriate quality standards especially in the production of foods, pharmaceutical products, and medical devices. GMP covers all aspects of the manufacturing process, product storage and transport, serial number tracking, and lot traceability.

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA). cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

Compliance, Competitiveness and the Global Market

Pharmaceutical companies in Bangladesh in order to remain competitive in the domestic market and make inroads in the international market are required and should comply with regulatory bodies to assure drugs are manufactured and consumers are guaranteed that each batch of medicines they take will meet quality standards so to be safe and effective.

The Directorate General of Drug Administration, Ministry of Health & Family Welfare, Government of the Peoples Republic of Bangladesh, issues GMP certificates. The Drug Administration issues GMP certificates following inspections carried out according to WHO prescribed standards.

In the international markets there are additional guidelines, standards, certifications and audits some of which are local GMP clearance of the host country, in the UK MHRA certificate and in the US FDA approval that has to be

acquired and maintained after successfully passing an audit. The pharmaceutical industry is constantly challenged to meet the rising standards of quality, and comply with rigorous regulatory requirements globally.

Software Automation and Technology

In order to adhere to sound manufacturing and best practices it is imperative that manufacturers uses software, hardware, equipment, machineries, systems, guidelines and processes that ensures that not only the end product, but data, information, and laboratory results is of the highest quality. All data and information should be secured, accurate, and reliable and only those personnel required viewing, adding, or updating a given piece of data are in fact allowed to access it.

Any delay in releasing a batch of drug is not only costly but the additional cost of compliance consumes additional resources of the company. It is therefore crucial during the manufacturing phase analytical data be collected, compiled, and submitted in a timely, accurate and reliable but secure manner.

In order to facilitate and advance the manufacturing and the quality control process which is an integral part of GMP, Technology and Business Solutions Ltd (TBS) www.tecbsl.com or pharma.tecbsl.com has developed a centralized web based information management system for Pharmaceutical QC / QA to store batch analytical results, manufacturing information, and to track, monitors analytical/manufacturing data in a secure manner. The system supports the management of analytical result data of Raw Material, Packaging Material, Water, Finished Products and Stability of Products.

This software application is currently operational at a major multi-national company in Bangladesh for the last two years.

The main functionality of the application is to track a batch life cycle from manufacturing to batch release. The system enables the printing of reports like Certificate of Analysis (COA), Trend Analysis, APR and other reports. The system has a powerful analytics/reporting capabilities and graphical dashboards which gives managers detailed real-time visibility into results and status of all laboratory testing.

Benefits and Advantage

In general the automated system benefits includes; reducing cost of business, improve manufacturing quality, reduce time to product release, introduce new products, comply with more regulatory requirements, withstand audits and most importantly reduce patient risk

The software solution is GMP, EU GMP Annex 11, and FDA-21 CFR Part-11 and ICH guideline compliant and has the following ICT complaint features:

Computerized System, Electronic Record, Data & Data Storage, Accuracy Check, Audit Trails
Change and Configuration Management, Security, Electronic Signature, Print outs and Batch Release

Maintaining both the highest quality levels and strict regulatory compliance, not only affects the bottom line, it can literally be matters of life and death for pharmaceutical manufacturers and customers alike.

To know more about this solution contact mushtaq@tecbsl.com or areja@tecbsl.com

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