PRESS RELEASE

Factorytalk Propel Thailand's Pharmaceutical Industry with Cutting-Edge eCTD Submission Management Milestone

1 July 2024, Bangkok -- Factorytalk, a leading digital solutions provider and consultancy for the life sciences industry, is thrilled to announce the successful upgrade and enhancement of Thailand's electronic Common Technical Document (eCTD) submission management solution. Since 2013, Factorytalk has been working with the Thai Food and Drug Administration (FDA) to digitally transform Thailand's submissions away from paper and manual processes by bringing in the latest technology. The solution streamlines the submission process, and centralises the administrative functions while adhering to eCTD requirements.

Regulatory submissions have always been a daunting yet compulsory process for the life sciences industry, the efficiency of which has significant impact on the overall pipeline of medical products introduced to the country. Thai FDA first introduced eCTD submissions in Thailand with cooperation with Factorytalk to alleviate the problem, and through this major update, we aim to lessen the complexity and time it takes to register pharmaceutical products. The project prioritizes tackling three critical pain points to the benefit of all parties involved.

Firstly, reducing the length of the submission review process overall, which was longer than desired. The new digital workflows implemented reduce manual and redundant processes, and an upgraded eCTD review tool has been made more accessible to alleviate previous constraints and bottlenecks. As a result, the industry can expect a significant reduction in the time submissions take pending approval.

> "The fact the Thai FDA uses the same solution trusted by regulators around the world including the US, Canada, EU, China, Australia, etc. ensures that the solution comes with best-in-class data security and integrity, as well as a solid development roadmap to further improve the submission process in the next 5 – 10 years such as eCTD template 4.0 that comes with much greater flexibility compared to the current version (3.2) that could potentially open up a lot of possibilities; or Substance, Product, Organisation, and Referential (SPOR) data management."

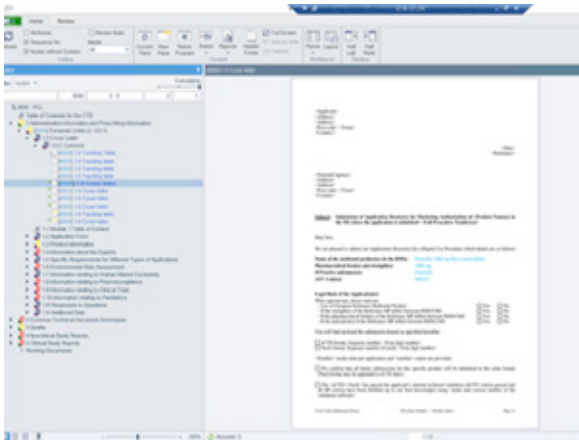
Teerapong Cheepchol
Factorytalk's board of director

Secondly, to improve visibility. Not only for the industry but also for the regulator themselves. Since there are several tools required to manage the whole Regulatory Management System, all systems are now integrated to ensure communication among the tools is done in real-time, without having to rely on manual data management. As the data is now synchronised, administrators can track progress from a centralized interface. Meanwhile, the industry will get a notification automatically whenever their submission's status changes.

And the last (but not least) pain point, improving accessibility to the eCTD submission publishing tool itself. After listening closely to industry feedback highlighting frustrations with the queuing time to access submission stations, the number of stations has been doubled providing an immediate solution, with other long-term improvements initiated and in the pipeline.

Factorytalk's aim is to help eradicate the reliance of paper from the whole life sciences industry. As relying on paper prevents companies transforming digitally towards Industry 4.0 and capitalizing on the improvements real-time data, process automation, and data driven decision making brings. As well as improving environmental sustainability by reducing waste from physical paper, printing, and the associated operational inefficiencies.

"Factorytalk's mission in regulatory submissions: empowering both regulatory bodies and industry players to navigate drug registration seamlessly. Our firm belief in the advancement towards eCTD submissions align with the proven success of global standards over the past two decades." said Mr. Teerapong Cheepchol, one of Factorytalk's board of directors.



Factorytalk is currently providing a submission tool and services to almost 40 companies in Thailand to prepare and publish eCTD submissions. As Mr. Teerapong mentioned, Factorytalk is looking for more opportunities to support both industry and the regulatory body. This year, Factorytalk is planning to hold free training sessions on how to use the latest version of an eCTD submission tool, as well as developing more packages that could potentially fit all businesses.

The solution Factorytalk provides is used by thousands of organizations, regulators included. Their client can ensure that confidential data will be managed properly.

"We have been working with our life science customers for two decades. Therefore, we are committed to leverage our experience for any deliverables. Nevertheless, our growth-mindset keeps us being innovative and striving for improvements to meet the evolving needs of the industry." Mr. Teerapong concluded.

Visit our websites for more information: **www.factory-talk.com**

About Factorytalk

Factorytalk are a leading digital solutions provider and consultancy for the GxP regulated life sciences industries, including pharmaceuticals, biotech, cell and gene therapy, medical device, herbal medicines, health tech, cosmetics, and F&B. Factorytalk has a team of experts operating across Asia, Europe, and the US from their offices in Bangkok, Thailand, and Manchester, UK. The company engages with over 200 customers worldwide and has offered validation, consulting services, and systems implementation for GxP-regulated manufacturing companies, government organizations, and regulators .