Skyland Analytics
Life Science Manufacturing Intelligence

REGENXBIO Selects Skyland PIMS™ as their Process and Product Data Management Software System

Boulder, Colorado – June 3, 2019. Skyland Analytics, a leading provider of cloud-based data analytics and data management solutions for the life science industry, today announced that REGENXBIO has selected Skyland PIMS Process Information Management Suite for management and analysis of product, process and patient data throughout their development and manufacturing supply chain. REGENXBIO is a global leader in the development of gene therapies in retinal, metabolic and neurodegenerative indication areas.

"Skyland PIMS was designed to meet specific needs of the biopharma industry related to collaboration and data security across external product development and manufacturing networks while meeting FDA standards for data integrity and validatability," said Robert Di Scipio, CEO of Skyland Analytics. "We are pleased REGENXBIO has chosen Skyland to provide data management and analytical tools that enable product development and manufacturing teams to keep pace with the remarkable science coming out of research and the life-changing results seen in the clinic."

The FDA expects more than 200 investigational new drug applications (INDs) per year by 2020 with many of them being cell and gene therapies.[1] This increase in approvals combined with vast amounts of data being generated throughout the product lifecycle of precision medicine therapies has life science innovators looking for better ways to organize and analyze product, patient and process data to ensure integrity and accelerate time to market.

Skyland PIMS is a purpose-built, cloud-based, 21 CFR Part 11 compliant workspace that centralizes management of critical development, manufacturing, patient and quality data required for business and regulatory reporting. It ensures data transparency and integrity throughout the product lifecycle and across the global supply chain.

[1]Commissioner of Food and Drugs - Food and Drug Administration Scott Gottlieb M.D. (January 15, 2019). *Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies [Press Release].* Retrieved from https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

About Skyland Analytics

Skyland Analytics helps biopharma manufacturers streamline drug product and process data management by offering cloud-based software solutions that ensure Part 11-compliant data transparency and integrity throughout the product lifecycle and supply chain.

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