



PRESS RELEASE

Hamilton Offers In-Depth Exploration of DSP Operation Units CPPs with New White Paper

(Bonaduz, 8/14/2023) - Hamilton has just released a comprehensive new white paper, "Biopharma PAT:Downstream Critical Process Parameters." This whitepaper serves as a powerful resource for biopharma manufacturers seeking to design efficient and robust DSP processes and ensure product quality, safety, and efficacy in biopharmaceutical production. The document is a compelling for downstream skid-builders, as well: multiple real-life examples are provided.

During the production (upstream) and successive purification and concentration (downstream) of biopharmaceuticals in a GMP environment, each product must retain the expected biological activity and potency in its intended therapeutic application. By defining their critical quality attributes (CQAs) and controlling the corresponding critical process parameters (CPPs) with appropriate process analytical technology (PAT), the biopharma manufacturers can achieve such a goal.

Process control requires in-line process monitoring. In downstream processing, however, in-line monitoring can pose significant systems design challenges. In this white paper, Hamilton explores the CPPs which are mandatory to control for each unit operation of the DSP skid train, such as: buffer preparation/dilution, protein A and IEX chromatography, filtration, and virus inactivation. Example and in-line sensors management tips are provided in order to benefit from the highest measurement accuracy.

"We often see our customers in biopharmaceutical manufacturing grapple with how best to choose and implement PAT that are both robust in scope and efficient in use," states Giovanni Campolongo, Senior Market Segment Manager Biopharma. "With this white paper, we seek to shed light on systems that can achieve this and provide



examples and actionable information on how to best implement in-line sensors to monitor downstream processing.”

To access the whitepaper, visit <https://www.hamiltoncompany.com/de/process-analytics/biopharma-downstream-cpp>

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About HAMILTON Process Analytics:

Hamilton Process Analytics, a division of Hamilton Bonaduz AG, pioneers open sensing solutions to enhance the understanding and control of critical process parameters, including pH, ORP, CO₂, conductivity, and dissolved oxygen as well as total and viable cell density. First introduced in 1989, Hamilton sensors are found worldwide in applications ranging from biopharma to power generation to brewing. Hamilton continues to lead the industry with new innovations such as intelligent sensor management via Arc wireless technology, and single-use solutions to significantly reduce risk of contamination. Each Hamilton offering is supported by a full portfolio of accessories including armatures, transmitters, cables, buffers, and standards.

Hamilton Bonaduz AG is the European counterpart of Hamilton Company, founded by Clark Hamilton in 1960 and headquartered in Reno, Nevada, USA. With more than 2,500 employees across global manufacturing facilities and subsidiaries, Hamilton is a leader in numerous fields including automated liquid handling robotics, automated sample management, medical ventilators, laboratory products, and process analytics.



Press contact:

Jansen Communications

Public Relations & Marketing

Birlenbacher Str. 19-21

D-57078 Siegen

Phone: +49 (0) 271 70 30 21-0

info@jansen-communications.de

www.jansen-communications.de

Company contact:

Hamilton Bonaduz AG

Via Crusch 8

CH-7402 Bonaduz

Phone: +41 58 610 10 10

contact.pa.ch@hamilton.ch

www.hamiltoncompany.com