

PDA Letter

Volume LVII • Issue 1

www.pda.org/pdaletter

Q1 2021

Editorials

Chair's Message: What has the year 2021 in store for us?	2
President's Message: A Year Like No Other	3
A Unique Year of Hidden Treasures	4

Features

The Moldy Nightmare: Questions and Answers, Part 1	5
The Moldy Nightmare: Questions and Answers, Part 2	8
FDA Initiatives Drive 21 st Century Advanced Manufacturing Technologies	10
The Role of Current GMPs in COVID-19 Vaccine Production	13

DEPARTMENTS

Biopharmaceutical & Biomanufacturing

Accelerating Biopharmaceutical Innovation in Health Emergencies	16
---	----

Supply Chain & Outsourcing

Think Big, Leverage and Cooperate to Get COVID-19 Vaccines to People Faster	19
---	----

People

Supporting Early Career Professionals	21
---------------------------------------	----

PDA Letter

Volume LVII • Issue 2

www.pda.org/pdaletter

Q2 2021

Editorials

Early Career Professionals – Kickstart Your Career with PDA!	2
Past Leader Spotlight: Nathan Kirsch, PDA President 1965-1966	3
President's Message: PDA Mid-Year Update	4

Features

The Modern Quality Professional Development Tool: Parts 1–3	5
COVID-19 and the Sustainability of the LAL Supply	14
Why Industry Cannot Just “Move Away” from the Dye Ingress Test	18
Breaking Down Computer Systems Validation in a Regulated Environment	20

DEPARTMENTS

Biopharmaceutical & Biomanufacturing

New Frontiers in Developing and Manufacturing Vaccines	22
--	----

Manufacturing & Science

Flexibility—the Future of Manufacturing	24
---	----

Quality & Regulatory

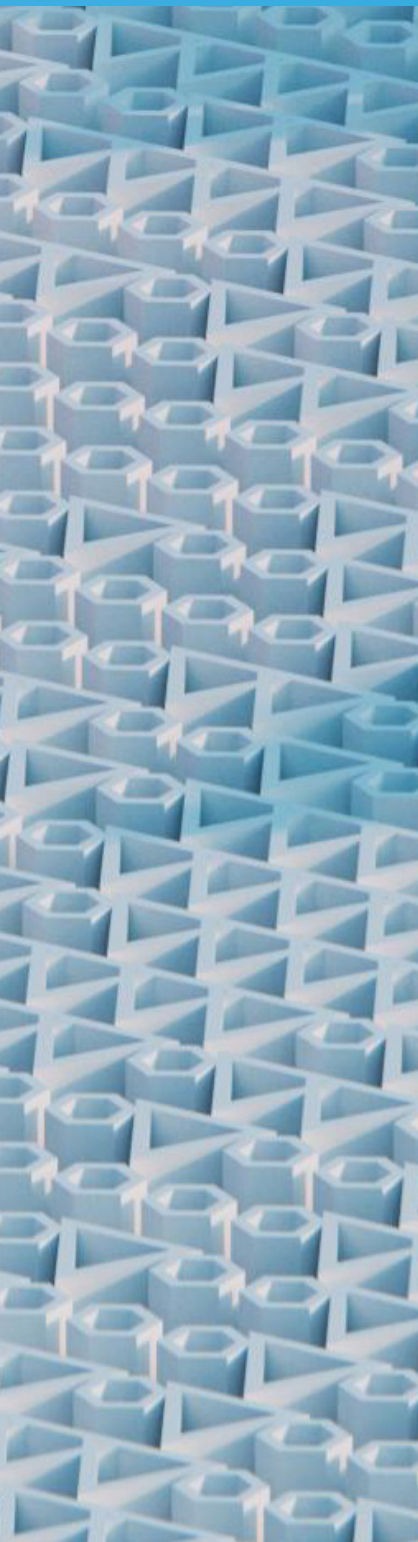
Remote Audits and Inspections May Be Here to Stay	26
---	----

PDA Letter

Volume LVII • Issue 3

www.pda.org/pdaletter

Q3 2021



Editorials

PDA's Critical Role in Advancing Manufacturing Science	2
Guest Editorial: Covid-19 Vaccine and High Stakes of Quality	3
Three Past Chairs Discuss PDA Careers	5
Past Leader Spotlight: Fred Carleton, President 1977-1979, Executive Director 1988-1991	6

Features

How Close Are We To Closed Processing?	7
COVID-19 and the Need for an LAL Alternative	10
COVID-19 Puts Focus on Airborne Virus and Pathogenic Microorganism Detection Methods	13

DEPARTMENTS

Manufacturing Science

COVID-19 Related Shortages of Manufacturing Components – There is a Way Through!	15
--	----

Quality & Regulatory

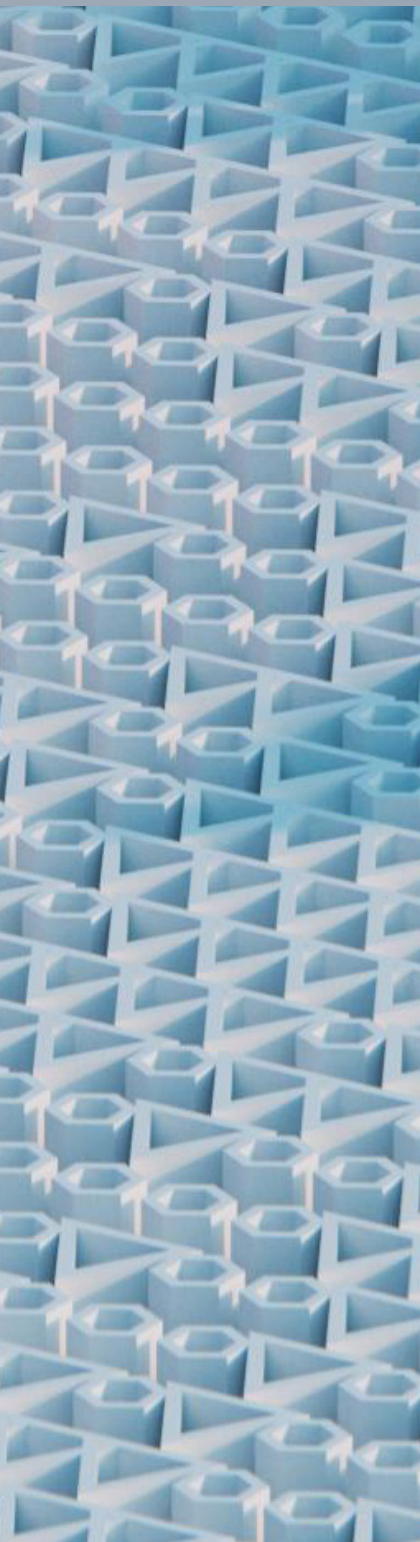
Virtual EMA Multistakeholder Meeting on Drug-Device Combination Products	18
Four Scenarios of Regulatory Relief from PAS and CBE-30 for CCS and Component Changes	21
My Journey to Japan – Sort Of	23
How to Measure Quality Management Maturity	25

PDA Letter

Volume LVII • Issue 4

www.pda.org/pdaletter

Q4 2021



Editorials

- Past Leader Spotlight: Rebecca Devine from FDA CBER
to PDA Chair 2

Features

- Zero-Particulates Goal Promotes Continuous
Improvement 2
- Contamination Control Strategies:
You Have Questions, We Have Answers 4
- 5 Agreements for Your Future Culture 7

DEPARTMENTS

Aseptic Processing

- Annex 1 and the New Revision — Setting New
Expectations 9

People

- Thanks, Science! 10
- PDA Assists EMA with Survey about Supply
Challenges Related to the Availability of
Single-Use-System Components 13
- PDA COVID-19 Task Force 13