

PDA Regulatory Conference 2025

Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle

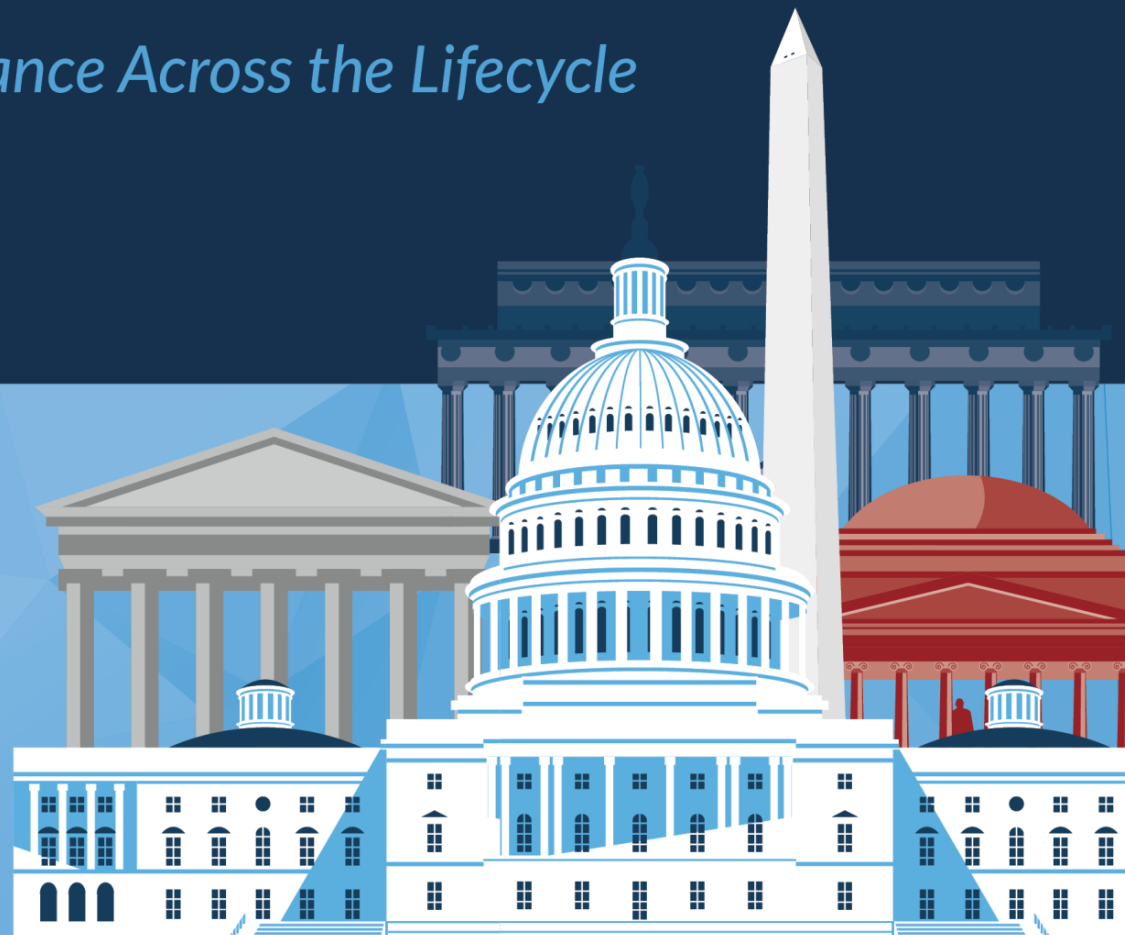
08-10 September | Washington, DC



**Parenteral
Drug
Association®**

*Connecting
People, Science
and Regulation®*

pda.org/regulatory2025
[#regulatory2025](https://twitter.com/regulatory2025)



The “Q” Also Applies to “U”

Presenter

Sanat Chattopadhyay

Executive vice president and president
Merck Manufacturing Division

Moderator

Irving Ford, MSc


PDA Regulatory Conference | September 10, 2025 | Washington, D.C.



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®

PDA Regulatory Conference 2025 *Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle* 08–10 September | Washington, DC



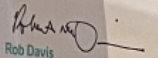
Safety first, quality always and inclusion for all

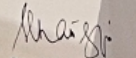
Safety first, quality always and inclusion for all are responsibilities that are equally important, the foundation of our reputation. It is what we expect within MMD.

Safety is a choice we make to ensure we do what is safe, are aware of any risks, and take any necessary action.

Quality is an obligation we undertake to ensure our products meet the highest standards so patients can rely on our medicines and vaccines.

Inclusion is our commitment to an environment of belonging, engagement, equity and empowerment so that all employees can feel safe, respected, heard and valued.


Rob Davis
Chairman and Chief Executive Officer


Sanat Chattopadhyay
EVP & President,
MSD Manufacturing Division

Quality is:

Our contract with patients

An interwoven ecosystem
where everyone must
feel responsible



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®

PDA Regulatory Conference 2025 *Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle* 08–10 September | Washington, DC

Investing in Quality

- ✓ **Intentional and strategic**
- ✓ **Cannot be rushed**
- ✓ **Strengthens your future**



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®

PDA Regulatory Conference 2025 *Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle* 08–10 September | Washington, DC

Quality = **Patient-first** Mindset

Cultural to the organization

Our primary job is to
deliver for patients

Integrity

We try never to
forget that medicine
is for the people. It
is not for the profits.
The profits follow,
and if we have
remembered that,
they have never
failed to appear.

GEORGE W. MERCK



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®



Quality requires:

Reliable, compliant supply
from all suppliers
(internal and external)

**Compliance and
accountability are shared,**
regardless of step
in supply chain



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®



Quality and **Digital** Transformation

**Digital tools exponentially
strengthen quality management**

**Robust data and real-time
monitoring are key**



**Parenteral
Drug
Association®**

Connecting
People, Science
and Regulation®

PDA Regulatory Conference 2025 *Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle* 08–10 September | Washington, DC



Collaboration

Harmonization

Conversation



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®

PDA Regulatory Conference 2025 *Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle* 08–10 September | Washington, DC

Our vision for **2030** and the future



Fully automated facilities with real-time data and AI assistants



Zero deviations and seamless change controls



Improved public health



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®

Thank you!



Parenteral
Drug
Association®

Connecting
People, Science
and Regulation®

PDA Regulatory Conference 2025 *Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle* 08–10 September | Washington, DC