



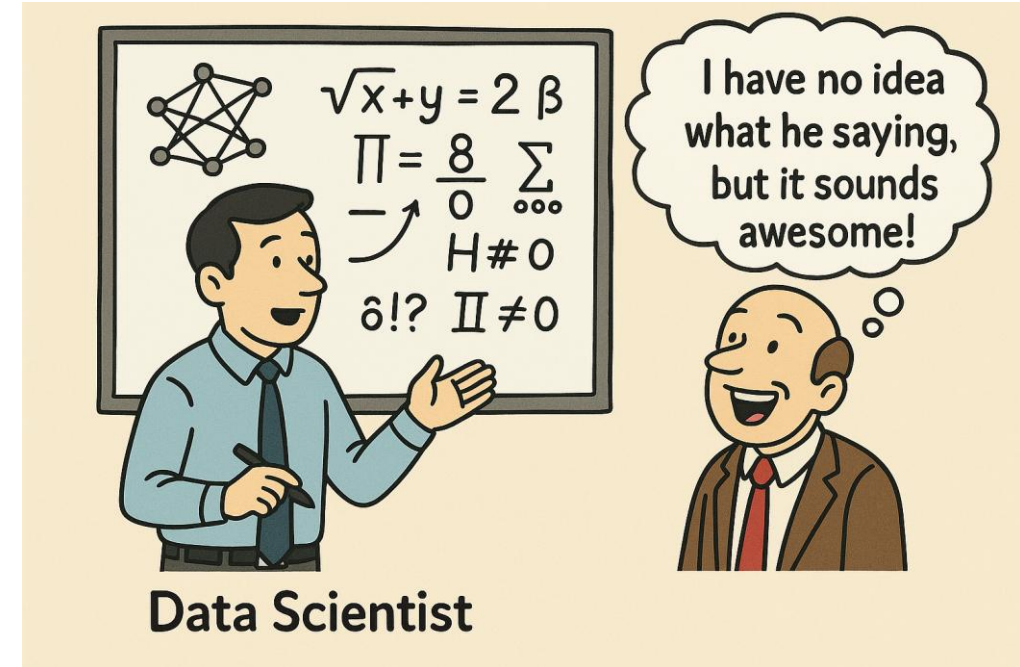
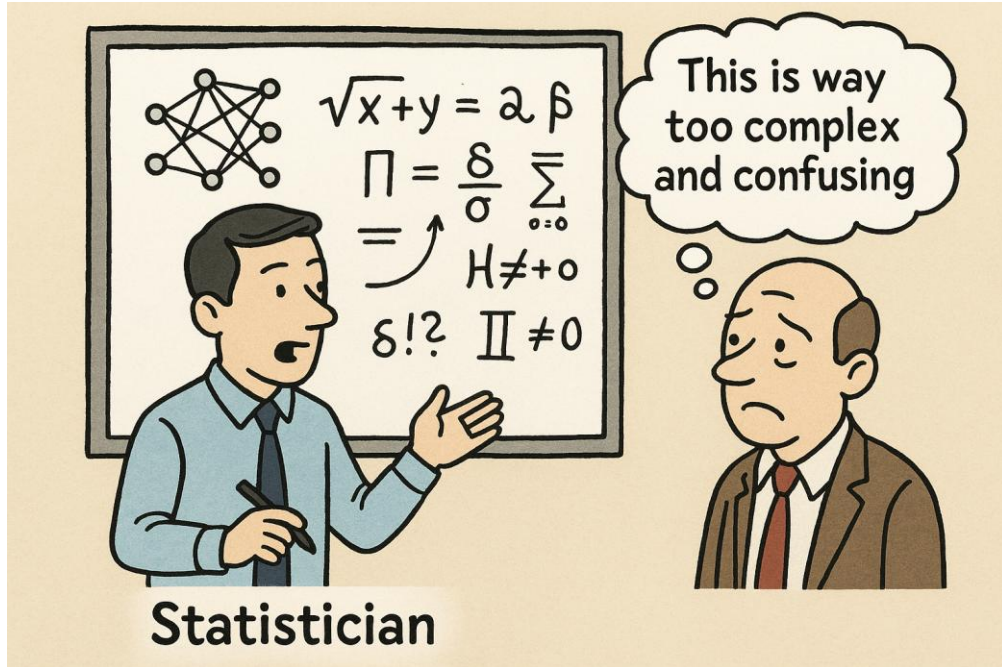
# CMC Statistics in a Data Science World

**Mark DiMartino - 11th IABS Statistics Workshop**

October 20, 2025

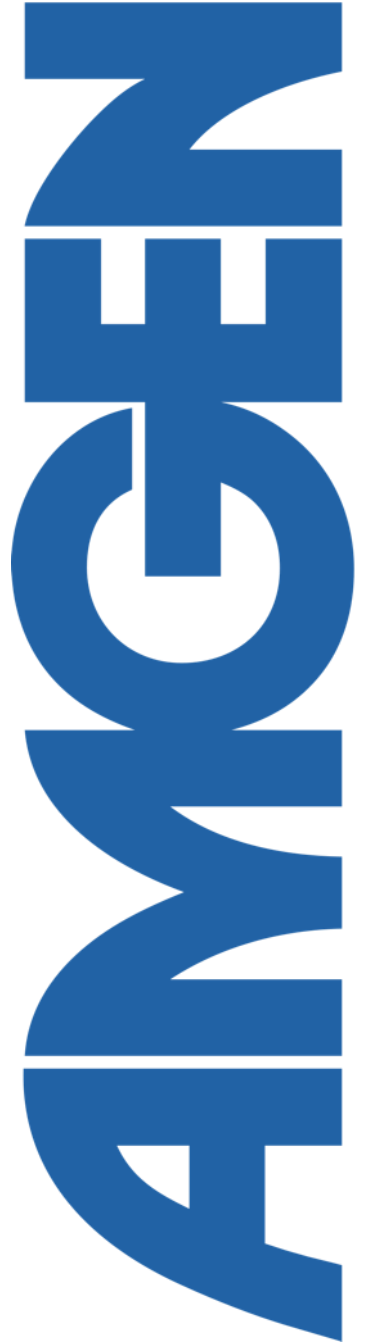
**AMGEN**

# Sometimes it feels like this.....

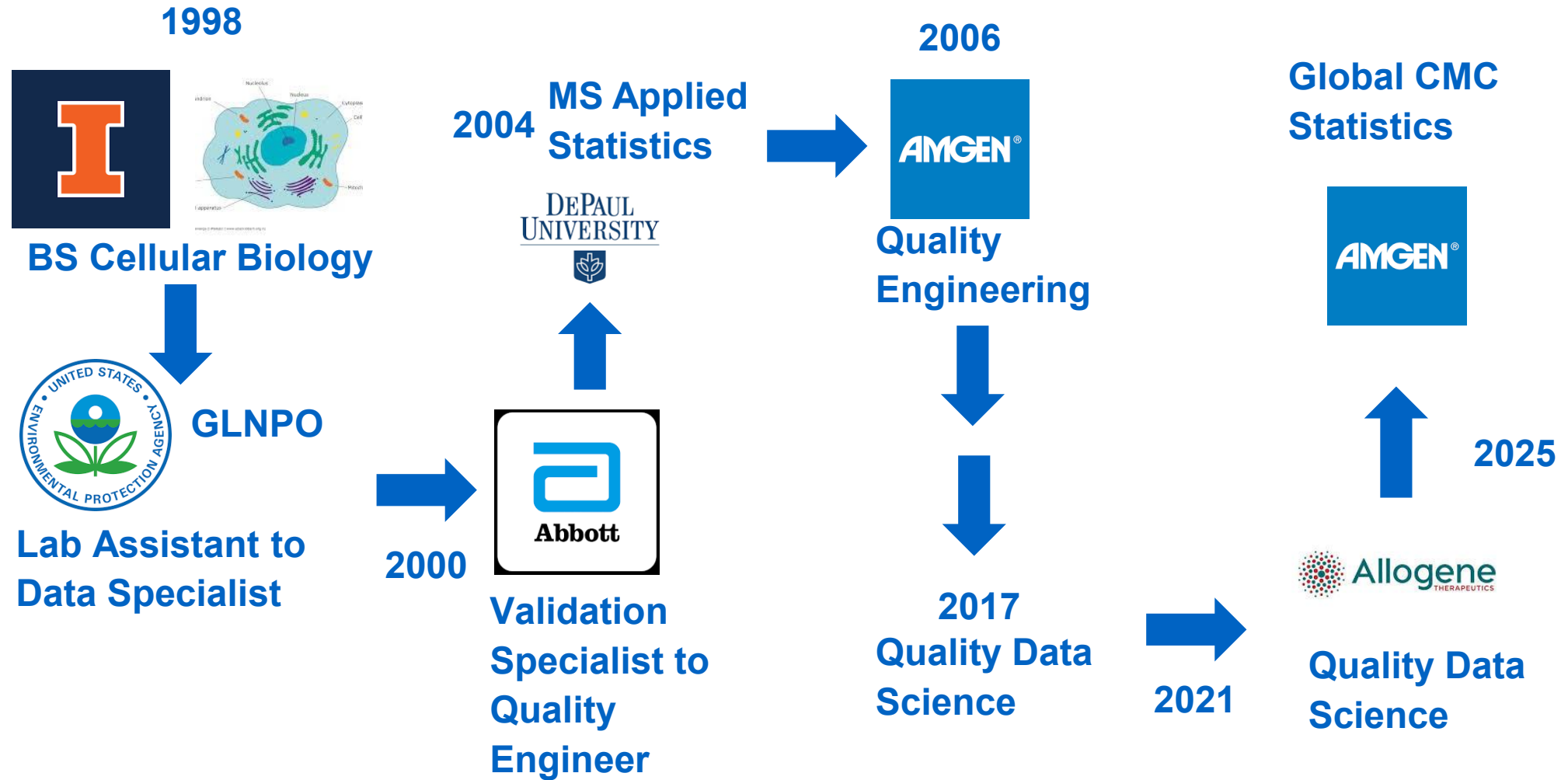


# Agenda

- 1 A little bit about my background
- 2 Data Science vs. CMC Statistics
- 3 Key Differentiators
- 4 Advocation Strategies

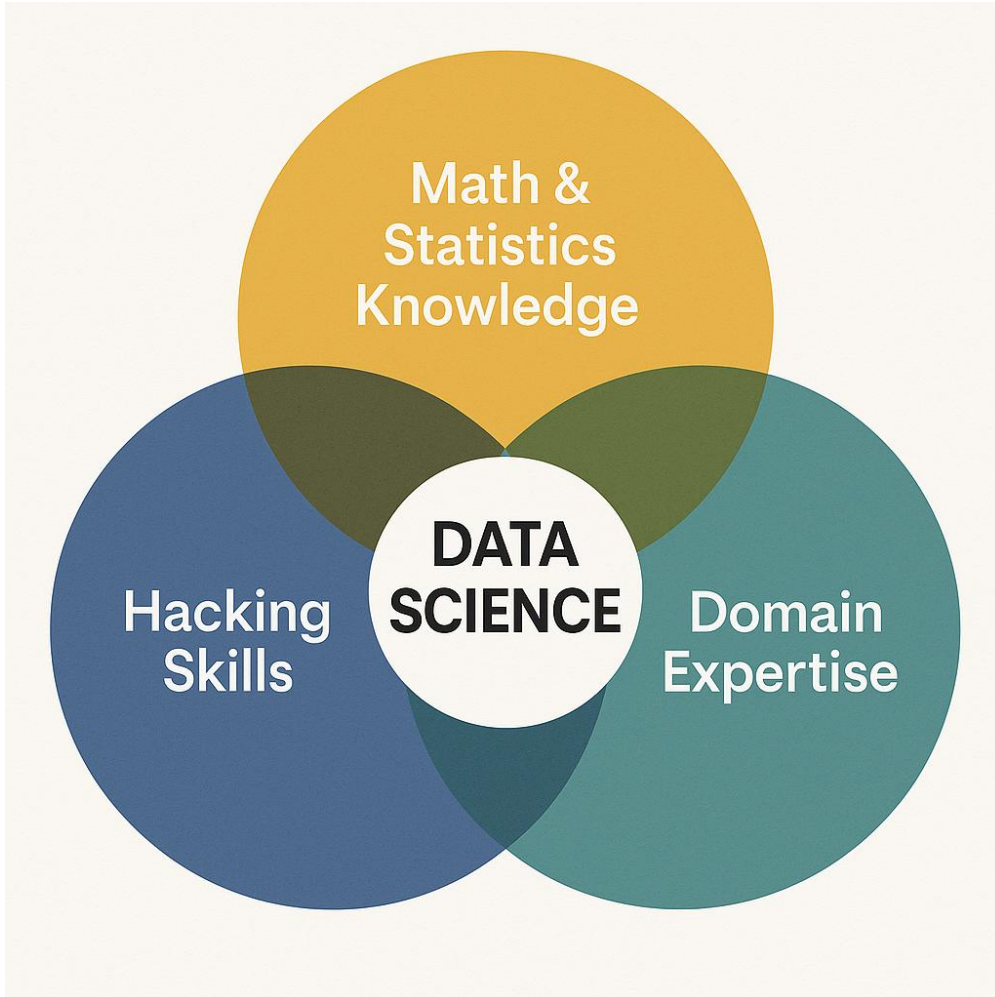


# A Little Bit About Me....

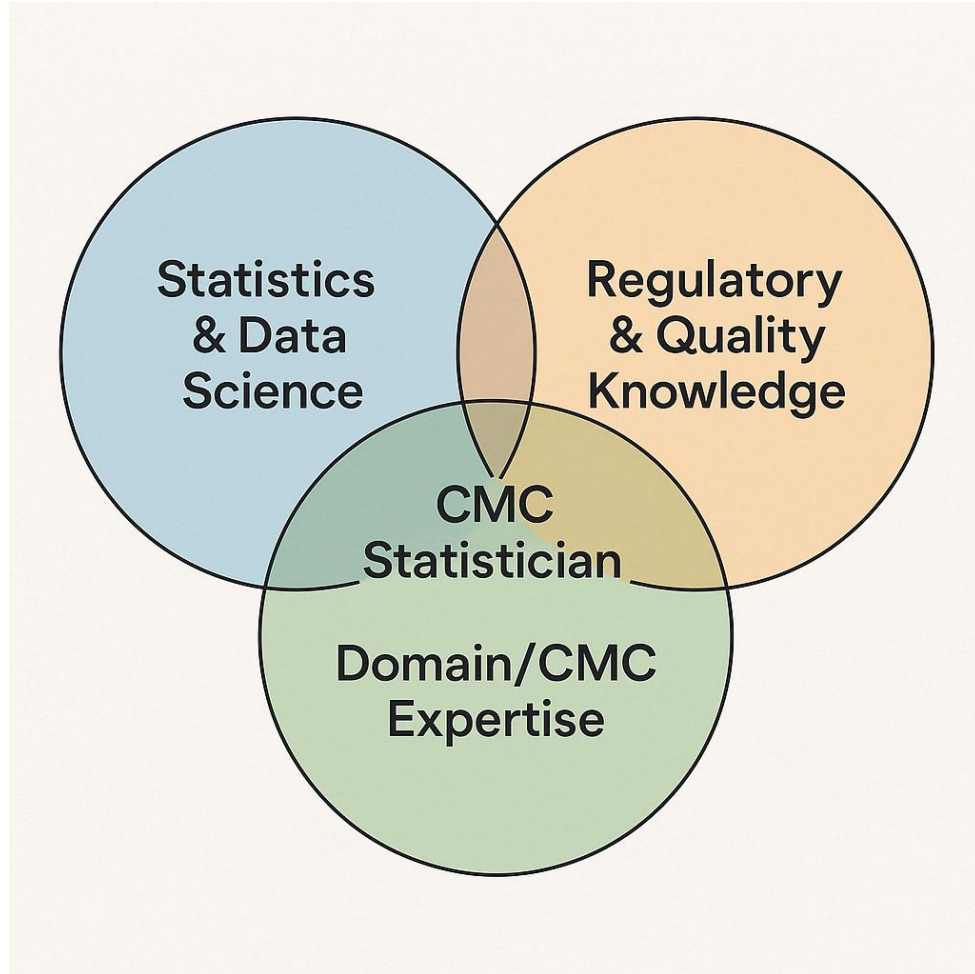


# So What is a Data Scientist Anyways? Lets Ask Chat GPT...

As likely to be found as...



# I asked Chat GPT to create a CMC Statistician Venn Diagram....



# What are perceived differences and similarities between the roles?

Aspect	CMC Statisticians	Data Scientists	Shared Skills
Primary Focus	Quality, safety, efficacy Identify and reduce variation	Insights & optimization – Digital Transformation	Statistical reasoning, data-based decisions
Regulatory Orientation	High – FDA/EMA/ICH compliance	Low to moderate – innovation focus	Awareness of compliance needs
Data & Methods	Structured data, DoE, SPC	Big/unstructured data, ML, AI	Programming (R, Python, SAS), visualization
Lifecycle Context	Entire product lifecycle	Project/problem focused	Cross-functional collaboration
Strengths	Process knowledge, regulatory credibility	Innovation, agility, advanced algorithms	Problem-solving, communication

# I see more similarities than differences, so how can that be accentuated?



## Regulatory Expertise

Highlight the need for defensible analyses



## Partner with Data Science

Balance innovation with rigor



## Adopt Data Science tools

Leverage ML, automation, digital trends,  
Utilize the lingo



## Domain Impact

Showcase product, process, and lifecycle knowledge,  
Integrate with teams as much as possible



## Advocate to Leadership

Connect work to outcomes and value



## Shape the Narrative

Position as guardians of quality and innovation

Lets dig in on how to do this

# Some strategies for advocating to leadership and shaping the narrative

## **Step out of your comfort zone**

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- Get involved in projects that are not purely statistical in nature
- Engage with leaders, seek out mentors
- Understand the business
  - Tour QC labs and manufacturing plants
  - Read about the science, ask questions
  - If possible, attend management reviews

## **Be visible and vocal**

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- Present work internally and externally
- Focus on using non-technical language, especially when talking to leaders
  - Faster approvals
  - Reduced costs
  - Fewer Failures
- Nominate work for internal rewards (for example Excellence in Operations or Innovation Awards)

## **Connect the dots for others**

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- Focus on the why when engaging clients
  - Tie to strategic goals
  - Enable decision making
- Become an enabler of innovation, looking for the best business solution as opposed to the best statistical solution
- Mentor non-statisticians, be seen as a trusted advisor

# In Conclusion...

- The role of CMC statisticians is vital, but it must also be visible.
- Perception = Reality: If others don't see our impact, they may assume it isn't there.
- We must change the narrative: from 'support function' → to strategic enabler of drug quality, safety, and innovation.
- By stepping out of our comfort zones, advocating to leadership, and shaping the story, we define how we are perceived.

Thank You!