A Joint EBF/DVDMDG Workshop: Scientific or Regulated Validation - a Tiered Approach?

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Some Admin Issues

- Philip Timmerman will chair the meeting, I will help moderate
- Any environmental issues (sound, sight, heat, etc.) please let me know
- Cell phones off or vibrate
- Use the microphones to ask questions and speak into them from about 3 inches away
- Why we are here today….

In the beginning, all was chaos…

… and the guidance you would ordinarily receive was:

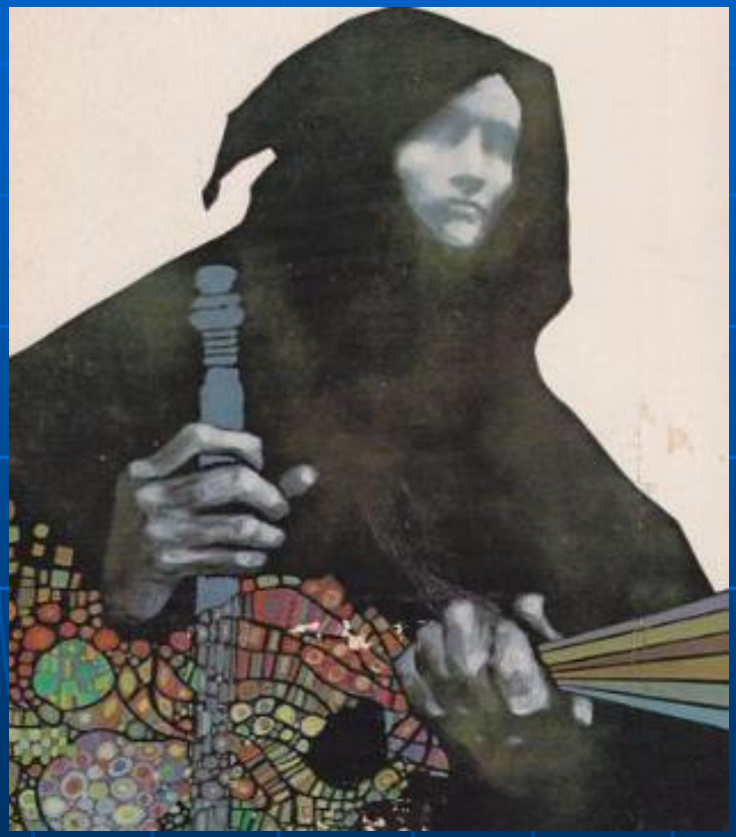
"Use your own scientific judgment!"

But…

…before 1990, I had worked for:

- 5 unique bioanalytical environments
  - U of L Grad. School
  - Sterling Winthrop
  - Yarest Laboratories
  - Wyeth Laboratories
  - RWJ PRI (J&J)
- 11 immediate managers
  - Some good, some zero, and some bad

…and then Crystal City happened!



From “The Traveler in Black” by John Brunner

- Initial reaction: No! Status Quo Initially Maintained
- 1992: Pharm Res paper, new boss, things started changing
- 2015 and CCII to CCV later:
  - BMV Guidance is now SOP
  - One size fits all checklist for both industry and regulatory agencies

…but, what happened to scientific judgment??

2015 Realities

- No two assays are alike
  - Always true but concept being lost
  - Bioanalysis is not a commodity!
- The requirements of different phases of drug development are different
- New game changing technology
  - Hyphenated techniques, especially LC-MS/MS
  - Computer capability
  - Automation
- Major financial challenges

Some things to keep in mind:

- A "checkbox" is wanted more than ever
  - Heaven help you if you get any inspection observations, especially if you are a CRO!
    - Perception that regulators and reviewers don't understand the effect of an FDA Form 483
    - "Death by 483"
  - Delays can cost $500k/day
  - Cost of hiring people who know what they are doing

Some more things to keep in mind:

- Whose scientific judgment will prevail?
- Is the current generation of scientists up to the challenge?
  - Specialization precludes seeing the whole picture
  - Ph.D./Post Doc training more "hands on" to generate samples for grants
    - Cheap pair of hands
    - Dumbing down of academic activity

…and finally:

- PK/PD is the glue that binds the disparate elements of the drug discovery and development process
- Bioanalysis is the glue that binds (almost always) the PK/PD processes

Bottom Line:

We have a new environment that demands bioanalysts be more efficient and to be smarter. But an increase in bioanalyst responsibility (with increased authority) is also needed.

Where do we go is why we are here today.