

# Sterility Assurance & Quality Risk Management Conference



**PDA**<sup>®</sup>  
Parenteral Drug Association  
Midwest Chapter



# Sterility Assurance & Quality Risk Management Conference

October  
25<sup>th</sup> & 26<sup>th</sup>





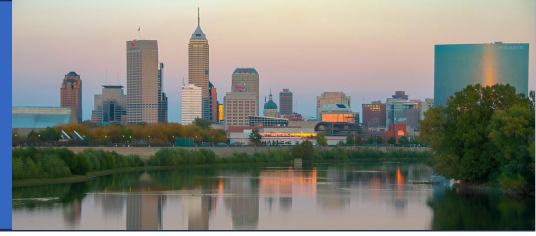
## What am I going to cover?

- Tips for risk collection and then risk management that focus on
  - Perspective on patterns and culture
  - Perspective on people and some of our bias
- Case Study on Tech transfer risk (focused on DP)



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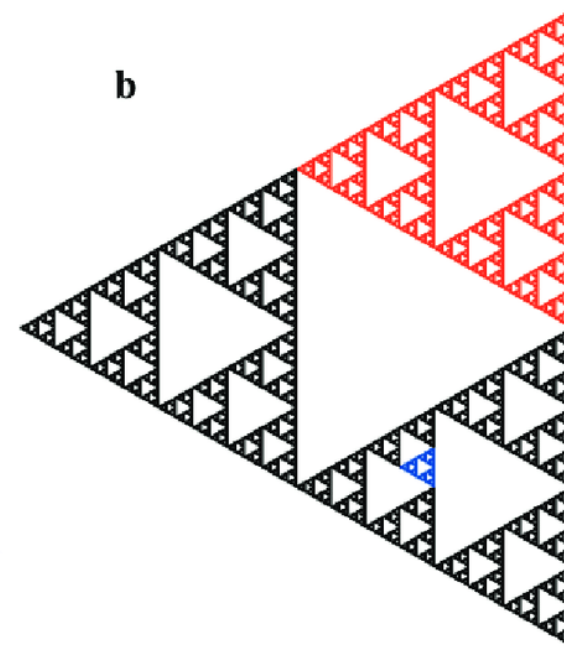
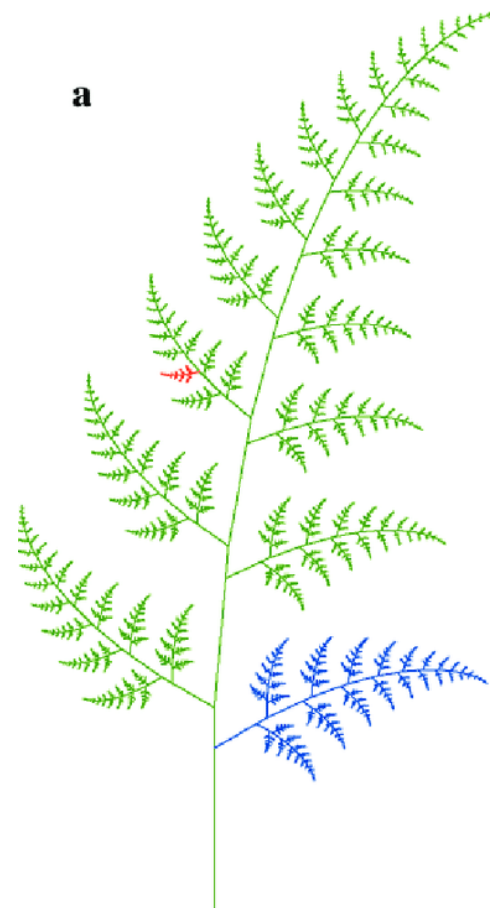
# Culture





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# Two Tips on Risk Collection

Where **YOU** can influence your culture



## Tip One

If you chair a meeting....ASK for new risks at the end!

- Save 5 to 10 minutes for a round table discussion at the end of the meeting
- And ask for updates on any new risks....
  - Give examples to get the conversation going
- After a few of these sessions, folks will become more comfortable talking about risks and learn how to see risks better in their day-to-day job.



## Tip Two

Train on risk in your new hire or onboard training at the Site.

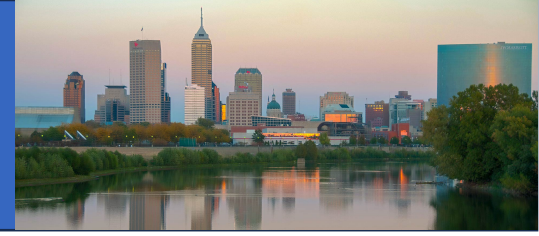
- The simplest way to cover this is at the same time you do pest control training with you new hires!
- Condition the team early to raise risks!



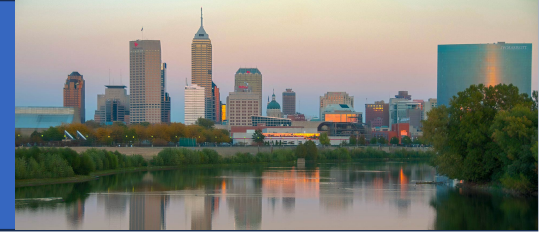


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# Teams and People



# So what is group think?

- The practice of thinking or making decisions as a group in a way that discourages creativity or individual responsibility.



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One man alone can be  
pretty dumb sometimes,  
but for real bona fide  
stupidity, there ain't  
nothin' can beat  
teamwork.

Edward Abbey

BrainyQuote®



## You are a leader, and you matter to the organization.

How good is your team meeting and if you are in quality your team probably chairs some of the following meetings?

- CAPA Review Board meeting?
- Human Error Review Board meeting?
- Risk Assessment Meeting?
- Risk Register Meeting?

Is there enough experiential diversity on your teams in your meetings to cover all the bases and maybe overcome any predispositions to bias?





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# Two Tips on Risk Assessing

Where **YOU** can influence your culture



## Tip One

Before you go to your meeting.....

- Did you think about your site's and team's culture first?
- Did you think about the experiential diversity of the group for the topic?
- If you know the team members, do you know their communication style and have you reflected on your own?



## Tip Two

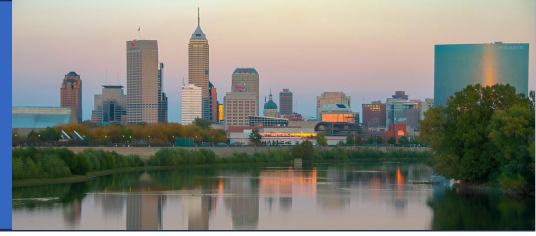
To enhance execution of the meeting....

- Assign a devil's advocate to the group to protect against group think! This person needs to pose a counter argument to the members
- Equalize the opinions between quiet and loud or introvert and extraverts through private collection – ask members a question about writing down their opinions on a piece of paper and then having one person read them out loud randomly
- Ask about views “on the borderline” too – provides insight to potential blindspots



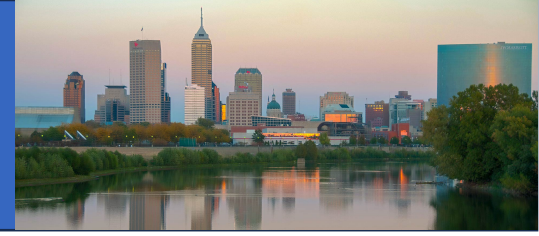
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# Case Studies





## Case Study 1, 2 and 3: Drug Substance to Drug Product

- New company team members biased to drug substance
- Decision made to get into filling
- A risk log was generated for the project



## Case Study 1,2 and 3: Drug Substance to Drug Product

- Installs and qualifies a filling line
- Executing gap assessments focused on:
  - sterility assurance, building aseptic intuition of the team
- Filled product – most of the product gets rejected during visual inspection, repeat, repeat, repeat.



## Case Study 1,2 and 3: Drug Substance to Drug Product

- Looked back at our risk assessments – and realized we missed characterizing the formulation for particulates and training operators to those conditions
- Filled again had rejects again
- New member added to team – asked to see buffer/water run visual inspection data....oops



# So what broke down?

Massive parameter shift in the operation from DS to DP

Historical team biased to DS backgrounds

DP = sterility got the most attention

Challenges with VI underserved





## Conclusion

### Widen the Funnel of Risks

- Spot check for risks in regular meetings – SLT, Tier Boards, Etc
- Familiarize your new hires in onboarding with Risk

### Be Thoughtful About Your Assessment Team

- Collect diverse experiences for your risk assessment
- Think about your team members (and your own) communication preferences and designate someone for counter points – and tease apart the “borderline” areas.

Do a lesson learned at the end and turn it into a lesson applied