OBJECTS IN MIRROR ARE CLOSER THAN THEY APPEAR
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)
Culture
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 your new hires!

• Condition the team early to raise risks!
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.
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?
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
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