

Plan for Managing a Seamless Promotional Reviewer Transition

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Disclaimers

The views expressed in this presentation are mine and are not an official position statement of my employer.

This presentation is for informational purposes only and is not intended as medical, legal, or regulatory advice.

I am an employee of Alkermes, Inc.

We don't work forever...



What is the Process?

Did/Do you have one?

When you started, how did it go?

What would you have liked to happen?

How would you best hand off to someone new?

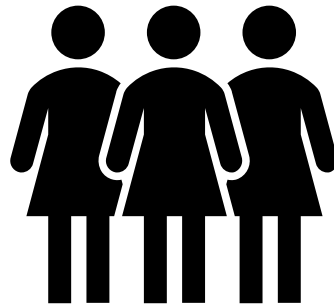
Goals



Maintain
Relationships



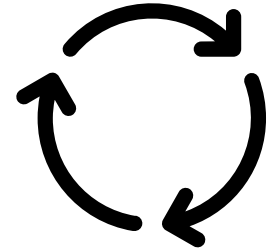
Nurture Trust



Redundant



Consistent
Lens & Voice



Seamless

Understand & Navigate Concerns

Reliable?

Timely?

What we're "used to"?

Same voice?

Same knowledge base?

Consistent lens?

Working style?

Available?

Will we get along?

Understanding brand history?

Are we training as we go?

Foundation/experience?



Develop & Execute a Plan

Meetings

- Allow for time outside the review session
- Preview materials together and separately to plan responses
- Schedule introductions with other reviewers and operations staff
- Shadow during review meeting/listen → Active reviewing behind the scenes → Defending comments during meeting → Taking over review

Communication

- Notify participants of intent to change or share
- Include other Reviewers, Project Owners, Meeting Coordinator, Editor, and other Operations staff
- Keep everyone abreast of status

Training

- Train on available resources including historical perspective, OPDP submissions and responses, sensitive topics, previous interpretations
- Ensure product knowledge
- Navigation of review application
- Meeting dynamics
- Procedural guidelines and work instructions

Logistics

- Delegate access – Veeva or system for review
- Transition of assignment when appropriate
- Ensure timelines are clear and respected

Execution

- When it's time, don't micromanage
- Despite best efforts, there are differences



To expect the unexpected shows a thoroughly modern intellect
- Oscar Wilde

Thank you

Time for Questions & Discussion