



Health
Canada

Santé
Canada

*Your health and
safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

Review Initiation Strategies in your Agency

November 7, 2012

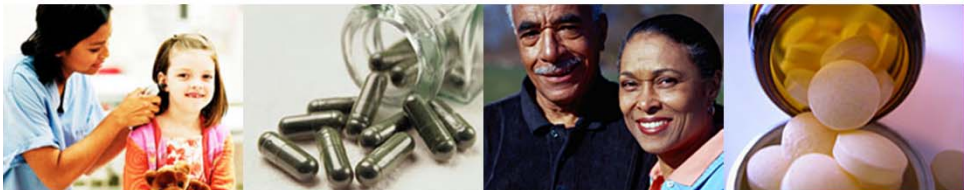
Caroline Vanneste, GRP Project Manager



Canada

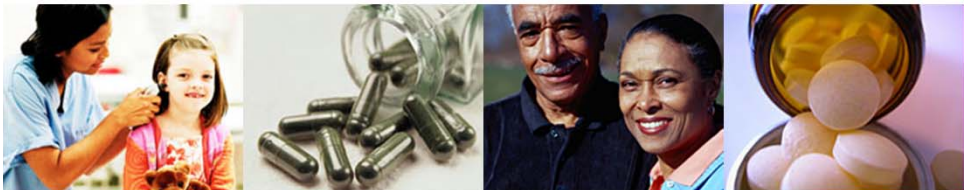
HC Review Initiation Strategies

1. Application screening / validation
2. Early identification of serious deficiencies
3. “Kick-off” meetings
4. Determining consultation needs



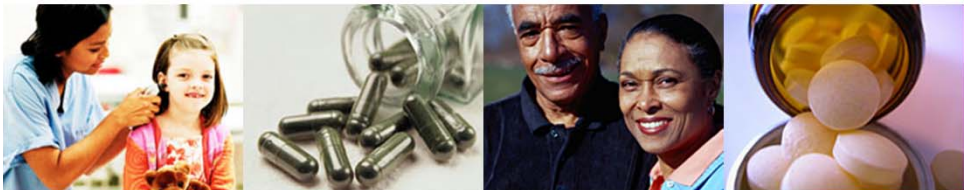
Current Practices in Your Agency

1. Do you screen / validate applications before they are assigned for review?
2. Do you have a mechanism for early identification of serious deficiencies early in the review phase?
3. Do you have kick-off meetings with the application review team?
4. Do you have consultants that you can use to provide assistance with the review of applications? If so, when is the need for a consultant identified?



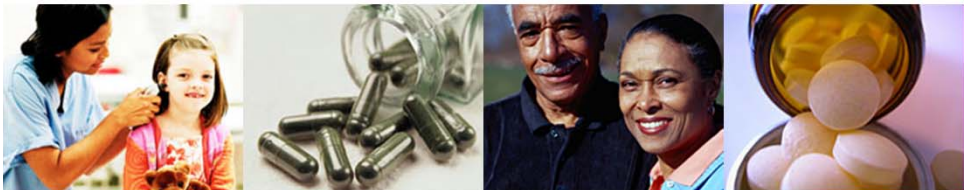
1. Screening / Validation

- Who? (e.g. regulatory staff, reviewer, manager, etc.)
- What? (i.e. how detailed is this step)



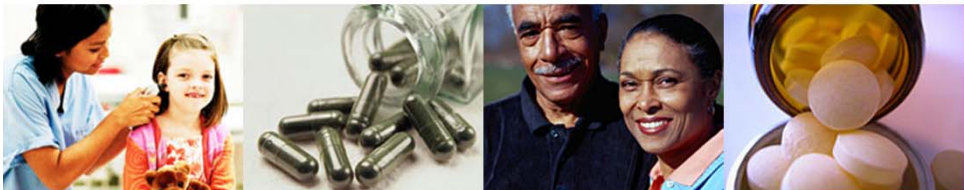
2. Early Identification of Serious Deficiencies

- Who? (e.g. regulatory staff, reviewer, manager, etc.)
- What? (i.e. how detailed is this step)



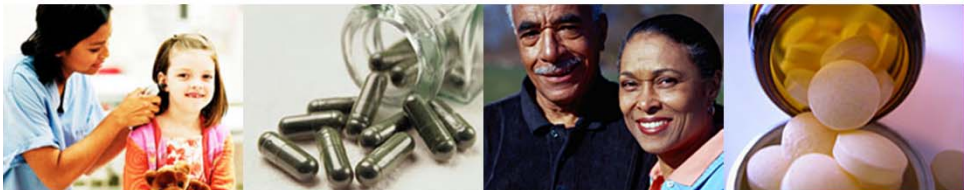
3. Kick-Off Meetings

- Who? (e.g. regulatory staff, reviewer, manager, post-marketing reviewers, inspectors, etc.)
- What? (i.e. what is discussed at the meeting)
- When? (e.g. upon submission of the application, after the screening step, etc.)
- Why? (i.e. what is the goal of the meeting)



4. Consultation Needs

- Who? (i.e. who is responsible for deciding to bring in a consultant)
- What? (i.e. what is the scope of the consultant's role, e.g. advisory or binding)
- When? (e.g. how much time is required to set up an advisory meeting, set up a contract with a consultant, etc.)
- How? (e.g. are external consultants paid)



Other Review Strategies

- Does your agency have additional review initiation strategies that you find useful?
- Are there other review initiation strategies that you think your agency should implement?

