

Avoiding Pitfalls in Regulatory Submissions

- A Summary -
 - 4 Pitfalls
 - 4 Solutions (common sense)
- But first..... a quiz -

What's a Pitfall?

pit-fall (pit'fol') *n.* **1.** a lightly covered and unnoticable pit prepared as a trap for people or animals. **2.** any trap or danger for the unwary.

Webster's American Dictionary (2001)

And the Answer is:

#2

A trap or danger for the unwary

Pitfall #1

Not Setting the Stage Early – for Where You Want to be at the End

- What kind of product – regulatory category ?
- Where will I sell ?
- Who regulates and when?
- What are the claims ?

Solutions

- Plan, Plan, Plan Ahead
- Talk to ALL potential regulators –
EPA – PMRA - CADPR
Identify and address the differences
Pre-registration Meetings
Follow-up to Confirm...and Update

Pitfall #2

Your submission is technically complete and accurate – but virtually unreadable.

The regulator's would rather have a root canal than work on your submission!

Solution

DO whatever it takes to:
MAKE IT USER FRIENDLY

- Make the transmittal letter a *roadmap*
- Use tabs, tables of contents, cross-references, etc.
- Provide submission on CD - with handy hyper-links for easy access
- If the US Tax Code is more readable than your submission – keep working!

Pitfall #3

Unstated and/or Unrealistic Expectations

“You need a decision by when??#@#!!”

Solutions

When discussing timeframes:

- Be clear – from the start
- Be fair
- Be consistent

Pitfall #4

Too Many Assumptions:

- Our product is “perfect”
- “They’ll remember”
- “They’ll understand”
- “It’s obvious; It’s self evident”

Solutions

ASSUME NOTHING

- Put yourself in the regulator's shoes...
- Give regulators the documentation they need to stand behind a decision
- Make sure all parties understand & agree – on timeframes, process issues, next steps, etc.
- Checkdouble check.....monitor – within reason

Bonus Solution....

After you've done everything you can think of to compile the perfect submission.....

then its time for:

Pitfalls – Be Gone[®]

- A new revolutionary product!!
- Guaranteed to rid your submission of all those Pesty Pitfalls!!
- USEPA – PMRA – CADPR Approved!!*
- “Safe” and “All-Natural”
- CALL NOW: 1 - 800 - R E G - E A S Y

* Conditional Registration Expires: 11 - 12 - 01

