

Common Pitfalls in Submissions

Industrial Perspective



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Common Pitfalls in Submissions: Industrial Perspective

- NUMBER ONE – Preregistration meeting
 - If Microbial: be aware of history of similar strains
 - If Biochemical: Meeting MAY be necessary for classification. Registrant to submit rationale and documentation
- When possible – use Joint Reviews with US EPA, PMRA and maybe DPR

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- Learn who your RAL will be and work with that person.
- Request waivers when appropriate
 - Scientific rationale needed
 - If joint review, may not be accepted by all Agencies
 - Ensure that all waiver requests and responses are sent to OTHER Agencies
- Send dossier by courier or hand-deliver: do not use regular mail if possible – use correct address, departmental numbers, etc.

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Regarding the dossiers:

- Format per 86-5 and comparable in Canada
- Use all needed and proper forms – on internet
- Change fonts to aid readability
- Use only clean copies, xerox carefully – good margins, etc.
- Keep CBI in separate, clearly marked section
- No CBI in cover letters (help the Agency by keeping CBI to minimum)
- Double, and then triple check for errors – use independent person

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- Tolerances – or exemption from requirement of a tolerance
 - Maybe eligible for waiver of fees
 - Use recent FR notices as a pattern
- Efficacy
 - Required to submit to PMRA and DPR, may be required with BPPD (Public Health)
 - Data may include: 2 years; phytotoxicity; dose rate response; statistical significance.