The Regulatory Pulse

In conversation with the experts

A guide with regulatory insights on registration of microbial bioproducts

Value Assessment

Essentials of data generation and dossier development

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Editor's Note

Dear Readers,

We proudly present the third edition of our regulatory guide, focused on the efficacy chapter for microbial bioproduct registration. This edition explores what regulators truly look for when assessing a product's real-world performance - moving beyond laboratory outcomes to demonstrate consistency, scientific rigor and value under practical use conditions. We have integrated the most recent guidance from the Pest Management Regulatory Agency (PMRA) on value assessments, ensuring that this resource reflects the latest expectations for efficacy data, data organization, and scientific justification.

To enrich this edition, we have included an exclusive interview with Dr. Laura Reyes, whose expertise in Integrated Pest Management and microbial technologies provides insightful guidance for applicants navigating efficacy requirements

Finally, we are proud to showcase the Institute for Sustainable Horticulture, which continues to support industry partners by offering laboratory, greenhouse and field efficacy testing that meets regulatory expectations. This unique applied research capacity helps the potential registrants design high-quality trials, generate credible data and strengthen their value dossier submissions.

We hope this edition equips you with the clarity and confidence needed to develop strong, scientifically grounded efficacy packages for your products.

Thank you for your continued trust in our work.

Dr. Jaswinder Kaur

Spotlight Interview - In Conversation with

Dr. Laura Reyes

KAYA-KAYO Consultant - Regulatory affairs

Laura is a biotechnology engineer with a PhD in Plant and Environmental Sciences from the University of Warwick, UK. She completed her postdoctoral research at Kwantlen Polytechnic University in partnership with Bee Vectoring Technologies in 2023, where she worked on sustainable agriculture and biological control solutions. Originally from Ecuador, Laura now lives in New Mexico with her family, where she combines her experience in plant pathology, integrated pest management, research and teaching along with global registration of biopesticides as a member of KAYA-KAYO organization. She is passionate about advancing sustainable farming practices and supporting growers through innovative, science-based solutions.

Questions & Answers - Insights from the expert

The following interview was coordinated and edited by Dr. Jaswinder Kaur, Publication Editor.

1. **Starting with your journey, Laura, how did your background lead you to regulatory science and working with microbial products?**

Laura: As someone who has worked closely with biologicals in the field, I have seen how critical efficacy data is, not just to regulators, but to farmers. When I moved into consulting on registrations, I found that sometimes great products fail to meet regulatory expectations because their efficacy data is not framed properly. That's when I realized I could help bridge science with policy and support the registrants in this journey.

2. **What exactly do regulators mean when they talk about "efficacy"?**

Laura: Efficacy, in regulatory terms, refers to how well a product performs its intended function under realistic use conditions. Whether it's a pesticide, soil-inoculant or bio-

stimulant, regulators want evidence that the product delivers what is claimed on the label. e.g. if the claim says that it controls whitefly in greenhouse and field vegetables then the data should prove that the product delivers whitefly control safely, consistently and comparably or better than the existing alternatives.

3. Why is the efficacy chapter such a vital part of the registration dossier? Is it really a make-or-break section?

Laura: Absolutely. It's one of the most fundamental sections. This is where you prove your product works. Because it justifies the product's value and use. Without strong efficacy data, PMRA might deny registration or restrict label claims, and the product becomes commercially unviable.

And this chapter doesn't just showcase whether the product works — it builds the scientific narrative of *how*, *when*, and *why* it works across different crops, climates, and pests.

4. Is there any structure or format that registrants should follow to organize this chapter?

Laura: In general, the structure for efficacy data is fairly consistent with the guidelines used globally. So, it is practically the same for all countries around the world, except for the U.S.

PMRA follows DACO format — which stands for Data Code, it's how PMRA organizes its submission requirements.

5. You mentioned the DACO format. Could you please walk us through what the DACO format is, especially in terms of efficacy data?

Laura: Sure. The DACO format is a structured data submission requirement used by the PMRA for pesticide registrations. It is a data coding system that assigns specific identifiers to different types of studies e.g. efficacy, toxicology, environmental fate, etc. It ensures that studies are submitted in a standardized, electronic format to facilitate PMRA's review process.

For efficacy, DACOs are used in the 90 series specifically 9.1 to 9.4:

- 9.1 is the product label,
- 9.2 summarizes efficacy data and rationale,
- 9.3 includes detailed study reports,
- 9.4 is for published information, if you use any.

6. What exactly is PMRA looking for when it comes to efficacy?

Laura: They want to see that your product does what it claims - control, suppression, or repelling of pests and that it does so under realistic conditions. They want statistically significant results and consistency across trials.

To support a "control" claim, the product must consistently reduce pest numbers or damage to a commercially acceptable level. What is considered acceptable varies: for pests that damage the marketable part of the crop (like codling moth on apples), a high level of control is required. For pests causing less impactful damage, lower reductions may be acceptable.

If the product doesn't achieve full control but shows consistent reduction, a "suppression" claim may be appropriate. Suppression might be acceptable if the product has a novel mode of action useful in resistance management, or if it fits well into integrated pest management due to low impact on beneficial insects.

Beyond pest control, PMRA evaluates phytotoxicity and any potential impacts on rotational crops, especially if the microorganism is persistent, produces active metabolites, or could affect germination or growth of subsequent crops.

7. What kind of data is generally accepted to support those efficacy claims? Is it about quantity, quality, or types of these trials?

Laura: Unlike chemical pesticides, microbial pesticides often have unique modes of action, so the evidence must demonstrate that the microorganism effectively controls the target pest under real-world conditions.

It must include:

- Field trials: Any efficacy trials should be conducted in accordance with established scientific principles. Registrants can find general guidance in documents published by

EPPO (the European and Mediterranean Plant Protection Organization). These resources explain how to set up trials and what data to collect. That said, if you're submitting data for Canadian registration, you don't need to follow Europe's Good Experimental Practice (GEP) standards. GEP is a European requirement, but Canada's PMRA doesn't ask for it.

- Use history in OECD countries: Data from other OECD member countries (e.g., U.S., EU, Australia) can support Canadian registration when:
    - The target pest and crop are the same or very similar,
    - The agronomic and climatic conditions are comparable,
    - The formulation and label claims match those being proposed in Canada.

  PMRA may request a bridging rationale to show relevance to Canadian use conditions.

- Published literature: You can use trusted published research or government reports to back up your product's performance, especially when it's already well-known how the product works or it's been used successfully in different places for a long time. For example, *Bacillus thuringiensis* (*Bt*) has been studied around the world and is known to control caterpillar pests using special proteins like Cry1Ac. Since these proteins work the same way everywhere, and since field trials have consistently shown they're effective on many crops, you may not need to run new local tests if your *Bt* strain uses the same approach and targets the same pests. Additional local efficacy trials may not be necessary as the literature provides strong scientific support.

- Scientific rationales: When direct data is limited, registrants can justify efficacy through science-based explanations, supported by literature or related trial data. For example, data from lettuce may be extrapolated to spinach due to similar crop and pest characteristics.

- Even the Laboratory Bioassays (In Vitro Studies) and Greenhouse or Growth Chamber Studies conducted under controlled environment help assess efficacy before large-scale field testing. However, these studies are just supportive not mandatory.



8. Say you have got data from UK or the U.S. – what is the best way to position that for Canadian regulators?

Laura: In that case, you need to explain its relevance to Canadian conditions clearly. If non-Canadian data are being used, it is essential to demonstrate how the study conditions remain relevant to Canadian agriculture. The registrant must explain how the crops, pests, climate, and production systems in the foreign trials align with Canadian use conditions. For example, if a claim is being made for aphid control in cucumbers, the supporting data must show that the conditions under which those results were generated are biologically and agronomically comparable to those in Canada.

When using European trial data, the registrant should compare the study climate and production conditions with the Canadian eco-zone on the proposed label. Key similarities—climate, soil, cultural practices, pest pressure, and susceptibility—should be highlighted. Greenhouse data generated outside Canada are generally acceptable because greenhouse environments are comparable across jurisdictions.

Non-Canadian data can be supported through either a scientific rationale or a bridging rationale.
A scientific rationale explains why Canadian trials are not needed. It must show that:
• The pest behaves similarly across regions
• The product's mode of action is consistent
• Environmental conditions are comparable
• Biological and agronomic principles support extrapolation
Relevant literature and precedent registrations must be cited and submitted.

A bridging rationale compares accepted foreign data with Canadian conditions, focusing on crop type, production system, application method, pest biology, and environmental conditions. Limited trial data or literature may strengthen the comparison. For example, efficacy of *Beauveria bassiana* against greenhouse whitefly in UK tomato trials may be bridged to Ontario greenhouses when conditions and pest biology align.

Bridging can also justify extending a use to closely related crops or pests—for example, moving from loopers on cabbage to loopers on cauliflower or diamondback moth on cabbage—when the product has shown consistent performance across similar systems.

9. Are there some guidance documents available for designing field efficacy trials?

Laura: Yes, there are comprehensive guidelines available for designing efficacy trials to support the registration of microbial pest control products in Canada. These guidelines are primarily provided by Health Canada's Pest Management Regulatory Agency (PMRA) and are detailed in several key documents e.g. Value Guidelines for New Plant Protection

Products and Label Amendments". For more guidance, you can visit the Health Canada website (or see the links at the end of this document).

10. Are there any universal trial design requirements that apply across different microbial product types — whether it's an insecticide, fungicide, or nematicide?

Laura: Regardless of the product type, PMRA expects all efficacy trials to follow a set of standard design principles to ensure data quality and regulatory acceptance. The trials must include:

- Untreated control plots, which are essential for drawing valid comparisons.
- A minimum of three application rates is typically required — including 0.5x (half the proposed rate), 1x (the proposed label rate), and 2x (double the rate)— to demonstrate a clear dose-response relationship.
- Trials should be statistically designed, often using randomized complete block or split-plot designs, to account for field variability.
- Data must be collected from a minimum of three different locations or across two growing seasons to demonstrate consistency under varying environmental conditions.
- Additionally, trials should follow Good Experimental Practice (GEP) standards, with all relevant environmental parameters such as temperature, humidity and rainfall thoroughly recorded. However, GEP certification? is not required for PMRA.
- Finally, the level of pest pressure at each site must be clearly documented to ensure the results are representative of real-world scenarios and support the proposed label claims. For detailed guidance and to ensure compliance with PMRA's requirements, it is advisable to consult these documents and consider engaging with PMRA early in the Pre-registration consultation process. PMRA offers this consultation to provide feedback on proposed study protocols.

11. Could you please briefly explain what Good Experimental Practice, or GEP, means in the context of EPPO guidelines, and why it's so important for generating reliable efficacy data for plant protection product registration?

Laura: Good Experimental Practice, or GEP, under EPPO guidelines refers to a set of standards for conducting efficacy trials in a consistent, scientifically sound, and transparent way. It ensures that trials are properly designed and executed as I just mentioned. The trials must be documented, covering everything from selecting the right trial site and pest pressure to accurate application and data recording.
Following GEP gives regulatory authorities confidence that the data submitted is reliable and reproducible. This is particularly important for supporting the registration of plant protection products, where high-quality efficacy data are critical for decision-making.

12. What other types of benefits does PMRA consider?

Laura: While demonstrating effective suppression or elimination of target pathogen remains the fundamental requirement, PMRA looks at the bigger picture. The regulator considers several additional benefits that contribute to the overall value proposition of a pest control product, e.g. environmental safety, resistance management, compatibility with IPM programs, socioeconomic benefits, and support for organic production. Crop quality improvements and socioeconomic benefits for farmers - like reduced application costs or labour savings also matter significantly.

Similarly, if a product is stable for longer periods without the need for refrigeration, this attribute could impact product cost and confer a benefit to agricultural producers. A summary of any potential health, safety or environmental benefits that could result from the proposed use of biopesticide may be provided. For example, the applicant could indicate that the proposed use seeks to control a poisonous plant, a plant disease with harmful effects on humans/livestock (such as ergot) or an invasive species. A product with a higher potential for crop safety (lower phytotoxicity) or a broader spectrum of activity on pests would also be beneficial. Indicating the potential for the product to replace, or reduce applications, of chemistries with restricted use patterns would be useful.

Keeping this in mind, anyone applying to register a product in Canada should focus on putting together a strong, well-rounded case. It's not just about meeting PMRA's rules, it's also about showing why the product is valuable to Canadian growers. The best dossiers don't just list data, it should tell a clear story that ties together lab results, field trial performance, and real-world benefits. That way, it's easy for the regulators to see why the product works and deserves approval.

13. So just to be clear, if a product isn't the most effective, but it fills a unique gap in the market, can that still carry weight?

Laura: Absolutely. If you are offering the only biological nematicide for a specialty crop, or something safer than chemical alternatives, that uniqueness can be part of your value case. It's not just about knockdown rates; it's about real-world usefulness.

14. As we know, microbials tend to be a bit more variable in efficacy. What challenges does that pose for applicants?

Laura: Microbial products are living organisms, so the performance can fluctuate based on climate, soil microbiome, application timing, and even daily weather. That is why it's important to demonstrate not just that the product can work, but when it works consistently. Even if suppression is the goal, if it adds value to IPM or resistance management, that's still meaningful for growers.

15. Can you please unpack how extrapolation and bridging work?

Laura: These are two useful tools when you don't have Canada-specific studies. Although related, they serve different purposes and rely on different types of justification.

1. Extrapolation

Extrapolation involves using data from one crop or pest to support efficacy claims for another. This approach is acceptable when there is strong scientific justification demonstrating similarity in biology, agronomy, pest behavior, and product mode of action. Two major concepts support extrapolation: crop grouping and pest grouping.

A. Crop Grouping

Crop grouping allows data generated on one crop to support claims for an entire crop group or closely related crops within that group. Extrapolation works when:

- Growth habits and cultural practices are similar
- Pest pressure and location on the plant are comparable
- Spray volume and application timing align
- The product's mode of action is expected to perform similarly

The following examples will simplify the concept

- Extrapolating efficacy from lettuce to spinach, where growing conditions and pest behavior are alike.
- Using data from apples to support claims on pears within the pome fruit group.
- Extending efficacy within the citrus group, such as orange → tangerine or lemon/lime → grapefruit.
- Applying data from strawberry to lowbush blueberry when both fall within the same crop subgroup and share similar application patterns.

B. Pest Grouping

Pest grouping allows data from one species to support claims on other species within a related pest complex. This is justified when:

- Feeding behaviors are similar
- Life cycles overlap
- Susceptibility to the mode of action is comparable
- Application timing and rates are consistent

Following examples may include:

- Using data from one leafroller species to support claims across the leafroller complex.
- Applying efficacy data from *Helicoverpa armigera* (cotton bollworm) to *Heliothis virescens* (tobacco budworm), as both are noctuid moths with similar biology.
- Extrapolating from aphids to whiteflies, since both are sap-feeding, piercing-sucking insects, provided differences in life stage susceptibility are acknowledged.

For any extrapolation, it is crucial to address differences and provide a clear, evidence-based rationale demonstrating why the product should perform similarly across the proposed crops or pests.

2. Bridging

Bridging is different from extrapolation. Instead of moving across crops or pests, bridging uses foreign efficacy data from jurisdictions such as the U.S., UK or EU and demonstrates that the results remain applicable to Canadian conditions. Bridging is commonly used in biological product submissions, where:

- Mode of action is not dependent on geography
- Environmental requirements for efficacy are similar
- Production systems (e.g., greenhouse) are comparable across regions

Here, the registrant must compare foreign and Canadian conditions, addressing pathogen or pest biology, application timing and method, climate or greenhouse environment and formulation consistency and application rates etc. For instance, if a product was tested in California against powdery mildew on grapes, the data may be acceptable in Canada if temperature, humidity, pathogen biology and spray practices are comparable and if a clear scientific explanation supports the relevance.

PMRA is generally receptive to both extrapolation and bridging, especially when:

- The product aligns with integrated pest management (IPM) or resistance-management strategies
- The justification is transparent, well-supported and rooted in sound biological principles
- The registrant clearly links foreign or grouped data to how and where the product will be used in Canada

The key is providing a thoughtful, detailed rationale that demonstrates why the data whether extrapolated or bridged, appropriately supports the Canadian use pattern.

16. What is a pre submission consultation and does that help companies?

Laura: A pre-submission consultation is a service offered at no cost by Health Canada's Pest Management Regulatory Agency that provides regulatory guidance to registrants or applicants prior to the submission of an application to register or amend a pest control product. You can:

- Present your study plans,
- Discuss scientific rationales,
- Get feedback on label claims,
- And avoid costly mistakes down the road.

It's a great way to align your strategy with regulatory expectations. It is generally scheduled once you have got a draft plan and some data directions. However, it is recommended to have it even at a stage when you haven't much more than the name of the biological. You can get a framework of the data requirements and know what you need to do and what you don't need to do. Thus, it helps structure the work.

17. Who is qualified to conduct efficacy trials for biopesticides or conventional pesticides, and what do regulators look for in terms of credibility and data quality from those trials?

Laura: Efficacy trials can be carried out by a range of qualified organizations. One common option is a Contract Research Organization (CRO), which specializes in conducting field and greenhouse trials to support product registration. These companies are familiar with guidelines from authorities like PMRA and EPPO or others. Many of these organizations offer trials conducted under Good Experimental Practice (GEP), wherever required.

Agricultural universities or federal research centers often have the facilities and expertise to conduct trials that meet regulatory standards. Larger pesticide or biopesticide companies may also conduct their own in-house trials when they have dedicated R&D teams and facilities.

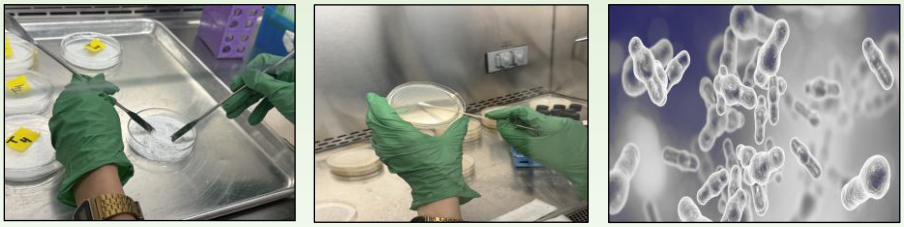
Regardless of who performs the trial, the data must be scientifically credible. Trials should include proper controls, replication, statistical analysis and be conducted on the target crop under relevant pest pressure. While GEP is mandatory in the EU**,** Canada does not require GEP**,** if the study follows established scientific methods. For registration purposes, the trial design, documentation, and analysis are what determine whether the data will be accepted.

The Institute for Sustainable Horticulture

driving reliable efficacy trials

The Institute for Sustainable Horticulture provides facilities to conduct early-stage product screening in lab and greenhouse trials. The institute also works in partnership with growers to conduct field efficacy trials that meet the standards required for regulatory submissions.

KPU offers specialized consultancy and regulatory support for agricultural biologicals, including pre-submission consultations, research permit application submissions, comprehensive dossier preparation, and post-approval compliance. Our team combines scientific, technical, and regulatory expertise to deliver high-quality documentation tailored for the agricultural bioproduct sector.



Microbial strain screening & Characterization

Greenhouse efficacy trials

Field efficacy trials

18. Before I wrap up, what are some common mistakes companies make in presenting efficacy data to regulators?

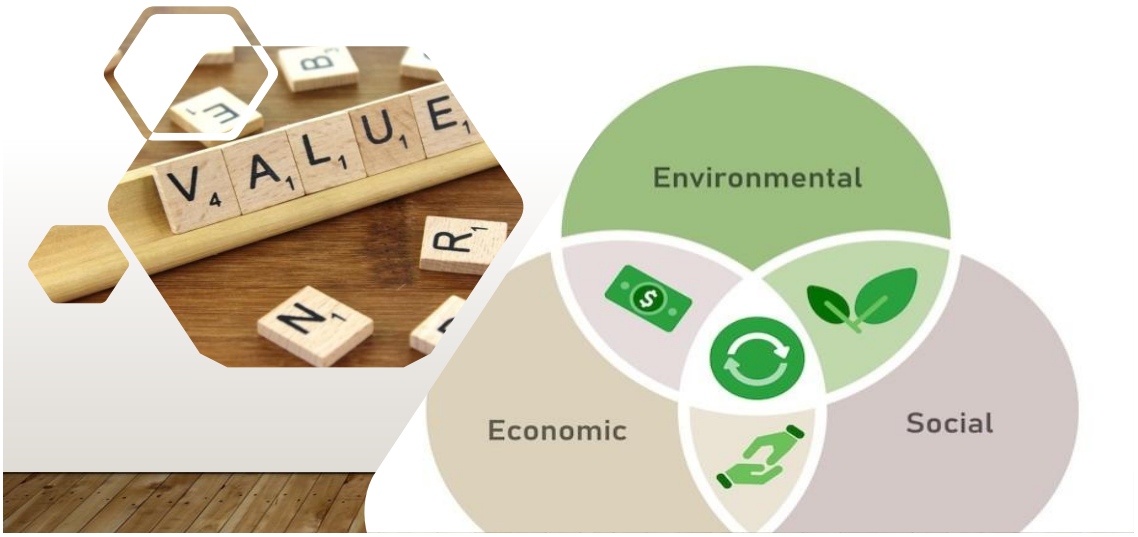
Laura: There are several**.** One of the most frequent is submitting raw, unprocessed trial results without any statistical analysis or interpretation. Regulators expect data to be analyzed statistically so that it clearly demonstrates how much the product works.
Another common mistake is misalignment between label claims and the data submitted. If the trials do not directly support the proposed claims, PMRA cannot validate them. Companies also sometimes forget to include untreated controls, which are essential for determining whether the observed effects are truly due to the product.

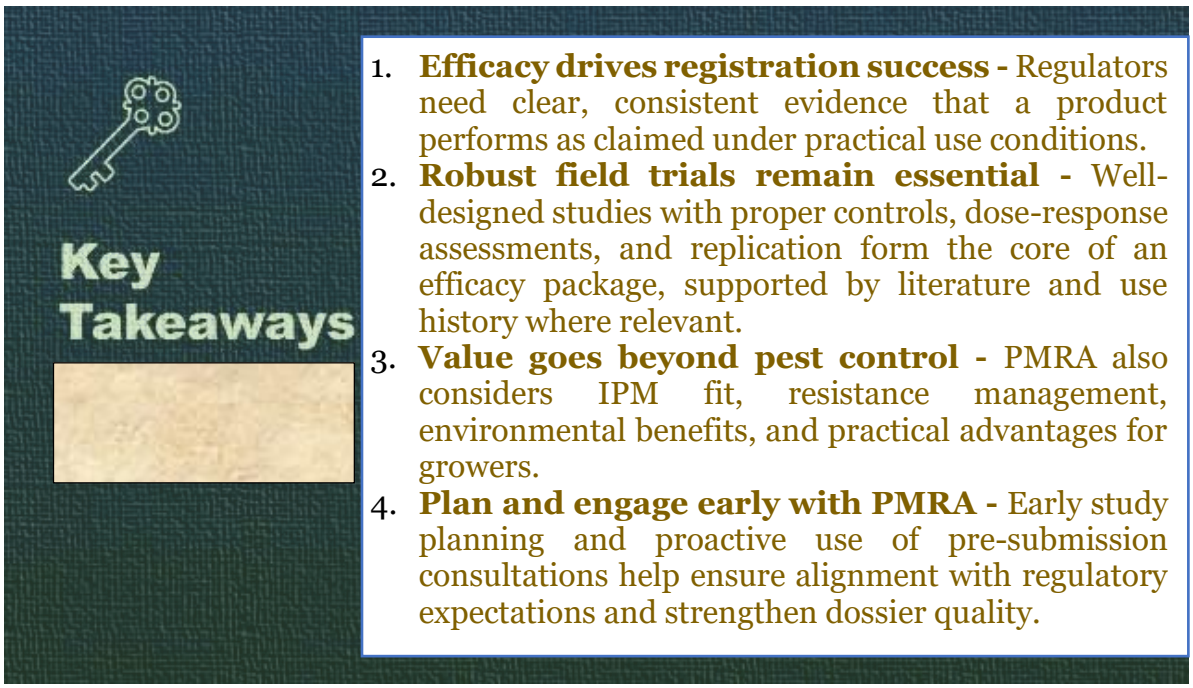
Using studies from non-representative climates or production systems without explaining their relevance to Canada is another pitfall. Without justification, foreign data is often considered unreliable. And finally, some submissions over-interpret results or draw conclusions that the data cannot support, which undermines credibility.

As mentioned earlier regarding the value of pre-submission consultations, engaging with PMRA early often more than once and planning trials carefully during product development can help prevent these costly and avoidable missteps.

19. Finally, what advice would you like to give to our audience regarding efficacy chapter to seek approval?

Laura: My key advice to anyone preparing the efficacy chapter is to plan early and align your trial designs closely with PMRA's expectations. Don't just submit raw data, you must interpret and present your findings clearly to directly support your label claims. Lastly, take advantage of PMRA's pre-submission consultation process to get early feedback and avoid costly mistakes. A thorough, well-organized efficacy chapter that tells a compelling, scientifically sound story will greatly improve your chances of successful registration.





Resources

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