VALSOURCE

Microneedle & Transdermal Delivery

001. Why ValSource for Novel Transdermal Product Development and Regulatory Consulting?

ValSource consultants have expertise to help navigate the complex regulatory environment for microbiological and production controls of microneedle array patches (MAPs) and other novel transdermal products.

For efficient product development, controls must be established early as they are critical to the timely and successful navigation of the CGMP pipeline. ValSource experts have been directly involved in the approval of Phase 1-3 products and held positions as microbiology experts in the US FDA Transdermal Working Group. From pre-IND stages through commercialization, ValSource is able to help.

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An Emerging Field

- MAP and other novel approaches to drug delivery without the use of traditional parenteral applications are an exciting area of development.
- The public health implications and patient satisfaction advantages will result in a remodeling of the current drug manufacturing and drug delivery paradigms.
- While significant progress has been made on the development of these products, there are still regulatory and product development challenges that must be addressed for a successful marketing authorization application.

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Industry Experts

- ValSource consultants have more than 50 years of combined experience in US FDA CGMPs for sterile and nonsterile pharmaceutical products including CDER, CBER,CDRH and combination products.
- Our experts have extensive experience both reviewing and approving Phase 1-3 novel transdermal products.
- Our consultants reviewed the very first submission for marketing approval of a MAP product to CDER (recommended approval for microbiological controls).
- Our team was also responsible for establishing the microbiological standards for these (and other) paradigm shifting pharmaceutical products.

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Ways We Can Help

- Identifying appropriate microbial control specifications (CDER/CBER/CDRH)
- Pre IND communications
- EOP2 meetings and planning for commercialization
- Negotiating specifications/release testing
- Document preparation
- Generating product-specific microbial data
- Applying USP methods/suitability studies
- Method development/validation
- Marketing submissions

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About ValSource

- Since 1996, ValSource has worked with hundreds of pharma, biopharma, and medical device organizations around the world.
- Our 350-strong talent force has proudly served our clients as advisors, trusted consultants, and highly experienced program managers.
- We offer a complete line of services to ensure client projects speed-to-market and success.

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Learn More

ValSource.com

info@valsource.com

610.269.2808

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Publications