Quality SmartSolutions

Questions About FDA Medical Device Regulatory Compliance?

Quality Smart Solutions Will Be Attending

Arab Health 2025

27 - 30 January 2025

Dubai World Trade Centre

Step-by-Step:

Canada's Infant Formula Registraion Process

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Health Canada's ***New Nicotine Rules***

Nicotine Replacement Therapies ***What's Changing in 2024/25***

UPCOMING
WEBINAR

"What is a DEL License and how it will impact your international cannabis sales?

Cannabis License Experts

Drug Establishment Licensing (DEL) and Exporting Cannabis

November 6, 2024

Hosted by
MARIE SWEENEY
Cannabis License Experts

GRAS EXPERTS

EFSA Transparency Rules for Novel Foods: A GUIDE

EUROPEAN FOOD SAFETY AUTHORITY

What Has Changed In the ESFA

NOVEL FOOD GUIDANCE?

GRAS EXPERTS

GRAS Pathways

When Expert Panels are Required

GRAS EXPERTS

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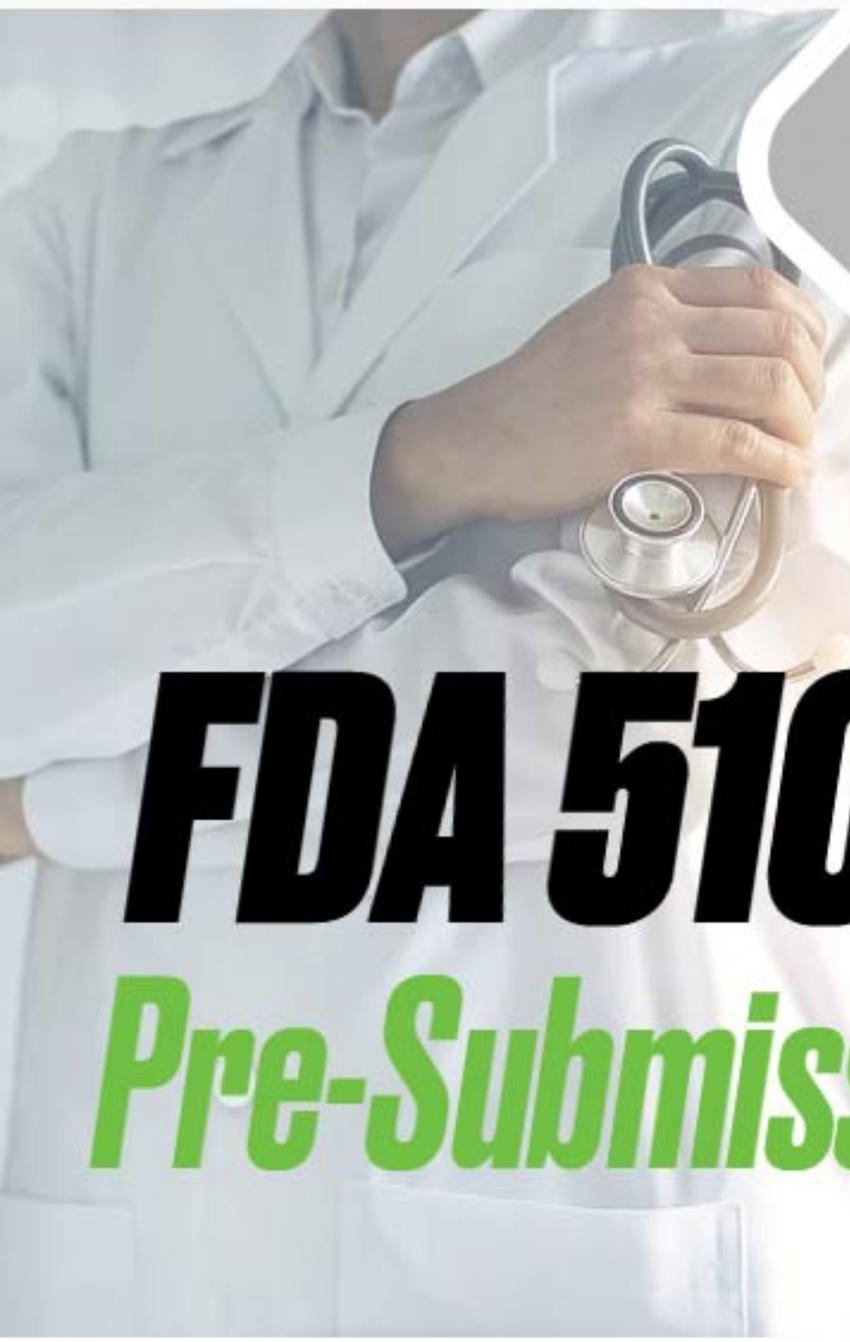

FDA 510(k)
Pre-Submission:

Steps for Medical Device Approval

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Questions About Medical Device FDA Compliance?

Quality Smart Solutions will be at

Arab Health 2025

TOMORROW

in Dubai

Let's Meet!

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Questions About Medical Device Compliance?

Quality Smart Solutions is at

Arab Health

2025

WE ARE HERE

Book a Meeting with us Today!

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Questions About Medical Device Compliance?

It is Quality Smart Solutions'

LAST DAY

at

Arab Health

2025

How to Master FDA AUDITS for Your Dietary Supplement Facility

New Nutrition LABEL REQUIREMENTS ANNOUNCEMENT

HEALTH CANADA

Quality™ SmartSolutions

FDA

Fees Summary

Quality™ SmartSolutions

2025

StratCann: Alberta Cannabis Regulator Corrects Recent Sampling Rule

Cannabis License Experts

Quality SmartSolutions

Fi Europe

Have questions about ingredient compliance?

We will be attending FI Europe in Frankfurt, Germany

November 19 - 21, 2024

Let's Meet!

Fi Europe

Event dates

19 - 21 November 2024

Location

Messe Frankfurt, Germany

Quality SmartSolutions

Questions About Food & Ingredient Compliance?

Quality Smart Solutions Will Be At FI Europe

TOMORROW!

in Frankfurt November 19 & 21, 2024!

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Good Manufacturing PRACTICES GUIDE

for Natural Health Products

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VIDEO:

STRATEGIES TO SAVE ON COSTS RELATED TO GRAS

GRAS EXPERTS

A DIVISION OF QUALITY SMART SOLUTIONS

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GRAS vs. NDIN

Generally Regarded As Safe

New Dietary Ingredient Notification

Legal Framework

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), applies to food additives.

Product Type

For conventional food ingredients.

Notification Requirement

Notification is voluntary; companies can self-determine GRAS status.

Basis for Safety

Based on long-term safe use or scientific consensus.

FDA Involvement

FDA involvement optional; reviews but doesn't approve.

Review Timeframe

No fixed timeline (usually within 180 days).

Legal Framework

Under the Dietary Supplement Health and Education Act (DSHEA), applies to dietary supplements.

Product Type

For new dietary ingredients in supplements.

Notification Requirement

Mandatory FDA notification for new dietary ingredients post-1994

Basis for Safety

Requires new safety data like toxicology or human trials.

FDA Involvement

FDA must review and respond to all notifications before marketing.

Review Timeframe

FDA responds within 75 days; marketing waits for approval.

GUIDE
FOR FOOD & INGREDIENT MANUFACTURERS

BEST PRACTICES FOR CONDUCTING GRAS STUDIES

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VHP REPRESENTATIVE VS. IMPORTER OF RECORD

KEY DIFFERENCES

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Do you have questions about food and ingredient compliance?

Quality Smart Solutions Will Be Attending

Vitafoods India

February 5 - 7, 2025

Jio World Convention Centre

Mumbai