

FDA.COM

ON-LINE INFORMATION PORTAL & DISCUSSION GROUPS

Discussion Forums on Conformity and Compliance for the Pharmaceutical,
Biotechnology and other Regulated Industry

Discussion Groups & Information Resources

- Part 11 Compliance
- Good Manufacturing Practice
- Good Clinical Practice
- Good Laboratory Practice
- Good Documentation Practice
- Equipment Validation
- Computer Systems Validation
- ISO/QS9000 Compliance
- Good Engineering Practice
- eSubmissions-IND, NDA, PMA
- Good Auditing Practice
- Regulatory Guidance
- Templates and Forms Repository
- Career Center & Resume Bank
- Advertising & Promotions
- Clinical Trials
- New Drugs
- Database Archives
- Guidance Documents
- Seminars & Conferences
- Global Market Place
- Classifieds
- e-Newsletters
- e-Bids



FDA.COM

GMP Publications

The Auditing Group



2016 - 2017
Prepared July 2016

FDA.COM

A POWERFULL NAME



1.2.2 FDA.COM (www.fda.com)

World-Wide Web portal for information pertaining to Food and Drugs.

FDA.COM

Food and Drug Assistance;
Resources for Industry and Consumers
Division of GMP Publications

John Cuspilich, Editor
Follow @john_cuspilich

GMP Publications On-Line Book Store • FDA, EU, ICH, Canadian & Japanese Regulations

Medical Device Quality Systems Manual

Part 11, 210/211, 820 and QSR Audit Checklist • On-Sale for \$15.95

Concise Step-by-Step Manual for Setting up Your Quality Management System • 780 Pages

ORDER TODAY!

CFR V&V Handbooks

Get an independent GMP (Mock FDA) On-Site Audit - More Info...

Retail Market Supplier GMP Compliance Certificate Program - More Info...

Drug

Medical Device

Food

Laboratory

Biological / Blood

Cosmetic

Part 11 / Validation

International

Receive the weekly FDA Rule Changes and updates - Sign-up your Colleagues! Enter your Email:

FDA Drug Handbook Qty

FDA Medical Device Handbook Qty

FDA Clinical Handbook Qty

Food & Drug Administration for Industry Links

- [Mock FDA Audits](#)
- [Guidance Documents](#)
- **Importing Directions:**
 - [Food & Cosmetics](#)
 - [Drug Products](#)
 - [Medical Devices](#)
- [Contact The FDA](#)
- [Search FDA Gov Site](#)
- [FDA Forms - Downloads](#)
- [FDA Meetings - Upcoming](#)
- [FDA Handbooks](#)
- [Drug/Device MedWatch](#)
- [CDER \(Biologics\)](#)
- [CDER \(Drugs\)](#)
- [Regulatory Affairs ORA](#)
- [CDRH Medical Device](#)
- [CDRH Device Advice](#)
- [Health Professionals](#)
- [Food - Nutrition Industry](#)
- [Cosmetic Industry](#)
- [For Patients](#)

Industry and Consumer Links & Resources

- [Recalls-Alerts-Warnings Recent - Archives](#)
- [Warning Letters](#)
- [Drug Approvals](#)
- [Report Problems](#)
- [FDA Consumer Info.](#)
- [Food-Nutrition](#)
- [Cosmetic Industry](#)
- [Health Topics](#)
- [Drugs & Supplements](#)
- [Medical Encyclopedia](#)
- [Medical Dictionary](#)
- [Medical News](#)
- [Medical Directories](#)
- [Medical Organizations](#)
- [COC A-Z](#)
- [Clinicaltrials.gov](#)
- [Center Watch](#)

Conditions - Diseases Links & Resources

- [Acne](#)
- [ADD and ADHD](#)
- [AIDS/HIV](#)
- [Allergies](#)
- [Alzheimer's](#)
- [Arthritis](#)
- [Asthma](#)
- [Autism](#)
- [Back Pain](#)
- [Birth Control](#)
- [Cancer - Breast](#)
- [Cancer - Prostate](#)
- [Cholesterol](#)
- [Common Cold | Flu](#)
- [Crohn's & Colitis](#)
- [Dental Health](#)
- [Diabetes](#)
- [Diet & Nutrition](#)
- [Ear Disorders](#)
- [Epilepsy](#)
- [Erectile Dysfunction](#)
- [Glaucoma](#)
- [Hair Loss](#)
- [Headache | Migraine](#)
- [Hemipium](#)
- [Heart Attacks](#)
- [Hemorrhoids](#)
- [Kidney](#)
- [Lyme Disease](#)
- [Men's Health](#)
- [MSA](#)
- [Multiple Sclerosis](#)
- [Osteoporosis](#)
- [Parkinson's](#)
- [SARS](#)
- [SIDS](#)
- [Skin Care](#)
- [Sleep Disorders](#)
- [Smoking](#)
- [Snoring](#)
- [Stress | Depression](#)
- [Stroke](#)
- [Vitamins](#)
- [Weight Control](#)

GXP Academy

GXP On-Site Training and Education
Regulatory Compliance

3 day - On-site - All Inclusive
GMP BOOT CAMP

• Drug, Device and Electronic Systems
• Binders, books & Certificates

A Division of GMP Publications, Inc., 847 News & FDA.COM

Most Popular Handbooks

- 21 CFR Parts 210/211 Drug GMP handbook.
- [210/211 - Part 11 Electronic Systems](#)
- [210/211 - with Keyword Index](#)
- [Part 11 & Parts 210/211 - with 210/211 Keyword Index](#)
- [ICH Q7 \(EU Annex 18/Part II\)](#)
- [210/211 with Drug Preambles](#)
- [Cosmetic GMPs - 11, 210/211, 700, 701 & 'Is it a Soap or a Drug?'](#)
- [Parts 11, 210/211 & 820 Elect. Book, Drug GMPs, QSR - \\$7.90 ea.](#)
- [GMP Standard Combo - Parts 11, 210/211, 820 & ICH Q7](#)
- [Multi - US GMP - Parts 11, 58, 210/211, 600, 601, 610 & 820](#)
- [EU GMP 1-9, US GMP 11, 210/211, 820 & ICH Q7, Q8, Q9 & Q10](#)
- [US-EU-Japanese GMP Handbooks](#)
- [GMP Master with PAT Guidance](#)
- [GMP Auditor's Basic Handbook](#)
- [Canadian GMPs](#)
- [EU Basic GMP Handbook Chapter 1 - 9 \\$7.90 ea.](#)

Discussion Groups

- [21 CFR Part 11](#)
- [GMP Good Manufacturing Practice](#)
- [GCP Good Clinical Practice](#)
- [GLP Good Laboratory Practice](#)
- [Medical Device - Quality Systems](#)

Retail Marketing Supplier GMP Certification Program

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GMPs

Good Manufacturing Practice
21 CFR, 11, 210/211, 820, ICH Q7

[Buy Now](#)

GCP - Device

21 CFR 11, 50, 54, 56, 807, 812, 814, 820, 920R & PMA

[Buy Now](#)

International GMPs

US, EU, ICH/Japanese GMPs
21 CFR/210/211, 820, ICH Q7
EU GMPs/ Chap 1-9
Japanese GMPs

[Buy Now](#)

GCP - Drug

21 CFR 11, 50, 54, 56, 812, 814, ICH 2A & 2B

[Buy Now](#)

Revenue Streams:

FDA.COM offers unlimited revenue possibilities based upon the project user requirements. The site has the capabilities to rival all other similar websites, with revenue potential possibilities such as, but not limited to;

- Advertisement Opportunities

Top Banner

- Quarterly Ads can start at \$3,000.00 per Month x 12 Months = \$36,000.00 annually. Conservative Estimate.
- Could also add rotating ad banner capabilities to include up to three (3) Vendors could bring in a potential revenue of \$108,000 annually
- AdSense Opportunities

Side Banners

- Quarterly Ads can start at \$1000.00 per Month x 12 Month = \$12,000.00 annually
- Up to Six (6) Rotating Alternating Side Banners = \$72,000.00 Annually
- AdSense Opportunities
- News Media Site for Food and Drug Assistance
- News Media supporting government activities for CDER, CBER, CDRH, CVM, ORA, DEA, NIH, HHS, CFSAN, etc.
- Consumer site of FDA.COM companion for the government FDA.GOV site
- Training and Development Portals
- Drug and Device Technology
- WebMD type of services
- Specific focus and Subscriber targeted feeds
- Advertisements for Business to Business Directory
- Companion site for Associations, Etc.

Direct Services:

- a. Providing Advertising revenue capabilities
- b. Social Media and Discussion Groups for Consumers and Corporations
- c. The next 'WebMD' – The United States knows WebMD, but the world does not, and now Food and Drug Assistance could be the next WebMD type of portal for the world.
- d. Food and Drug Assistance, A Business to Business portal for Food and Drug Industry. Links, references, assistances, discussion groups, and forums serving the regulated industry world-wide.
- e. Training Seminars and YouTube style of on-line training
 - GMP Training
 - CME Seminars
 - Referential Integrity to GXP Conferences
- f. Video and live televised FDA meetings and conferences
- g. Q&A Results Consulting for FDA Industry for Pay

Manpower

With the new expansion of the existing web portal, we are seeking additional manpower to staff the;

- Sales, Marketing and Advertising group
- Internet and Email Campaigns
- Website Development
- Graphic Designers

Equipment / Resources Required

- Dedicated Server (e-Commerce)
- Backup Redundant Server (e-Commerce)



1.2.3 The Associations for Industry and Consumers

Food and Drug Association – Food and Drug Assistance

FDA.COM mirrors itself after many of the Industry Associations such as ISPE.ORG, PDA.ORG, ASQ.ORG, and others.

The Association will be an 'International' Association designed for multiple languages.

The association will have both a 'free' and 'Paid' membership attraction, whereas if 'paid' the members will gain valuable access to focused information, guides, handbooks, and election data from many sources, much of which will be provided in exchange for initial free advertisements offered by the site, the handbooks and newsletters.

The Association concepts ensures that subscribers obtain only the information that they seek, depending and based upon their specific interests and needs outlined within their initial subscription questionnaire. The relationships will mirror the RSS feeds concepts (RSS - Really Simple Syndication).

The RSS feed can, for example, allow a user to keep track of many different websites in a single news aggregator. The news aggregator will automatically check the RSS feed for new content, allowing the list to be automatically passed from website to website or from website to user. This passing of content is called web syndication. Websites usually use RSS feeds to publish frequently updated information, such as blog entries, news headlines, or episodes of audio and video series. RSS is also used to distribute podcasts. An RSS document (called "feed", "web feed", or "channel") includes full or summarized text, and metadata, like publishing date and author's name.

There are dozens of Industry Associations, however, FDA.COM will be the first of its kind for Consumers seeking healthcare information targeting their specific needs along with industry.

The Website will direct the visitor to either the Industry section of the Consumer section.

Depending on the data returned by the subscriber through an interactive on-line form, the user will gain access to a wide array of information, data and publications, including GMP Publications handbooks specific to the requirement.

In addition, all Industry members gain access to free templates and guidance from GMP Help Desk.

Food and Drug Association for Industry

FDA Member based subscription services for Professionals who work within the industry and Consumers who seek up-to-date targeted FDA information.

There would be two main associations:

Industry

- a. Pharmaceutical
- b. Medical Device
- c. Biologics
- d. Food and Food Products
- e. Dietary Supplements and Nutraceuticals
- f. Cosmetics
- g. Veterinary Medicine
- h. Hospitals and Healthcare
- i. Blood/Cell/Tissue

For Industry:

Member Benefits

- Targeted Emails specific to each Member's interest along with;
- Targeted RSS Feeds specific to each Member's interest
- Access to Webinars and Seminars specific to each Member's interest
- Live access to FDA Meetings and Seminars pertaining to Member's interest
- Access to various Industry News, Technical reports, FDA Agency and Scientific reports specific to each Member's interest
- Jobs and Employment Portal specific to each Member's interest
- Volunteer Opportunities
- Business to Business (B2B) Interactive Resources
- SOP Libraries and Document Sharing at [2.2.12 SOP Library \(www.soplibrary.com\)](http://www.soplibrary.com)
- Validation Documentation Libraries
- Network Opportunities, Meet and Greets and Round Table Discussions.
- Access to Conferences and Tradeshows specific to each Member's Interest
- GMP Publications Book Store, Training and Audit Discounts
- **Updated CFR's specific to the Member's interest – GMP Publications**

GMP Publications provides millions of handbooks – Now, with an annual membership, Members will be provided with a new copy of the Federal Regulations specific to their industry every year. For a small annual cost, the Member will stay current with the industry's regulatory requirements, and will have access to an abundant supply of on-line information.

This Membership feature provides GMP Publications with additional Member information data for our Database. Below is some of the information which could be gathered.

- Member Name
- Member's Company (Industry Selection)
- Member's Title (Industry Selection)
- Member Email Address
- Contact Telephone Number
- Contact Mailing Address
- Contact Condition State (Consumer Selection)

This data will be owned, controlled and managed through the GMP Publications database administration.

Currently GMP owns over 21,000 GMP Publications Customer emails and personal/company information and over 60,000 email address supporting the GXP News e-newsletter.

This new business model will provide GMP with tens of thousands of new emails, personal and Company information and data annually.

Currently, GMP Publications sells thousands of handbooks weekly, with the new Business model providing the purchaser with the following options:

1. Annual subscription to automatically re-order the updated regulations on the anniversary of the original order. This option provides the user a discounted price for the new updated regulations.
2. Annual subscription to automatically re-order the updated regulations on the anniversary of the original order for each specific handbook owner. This option automatically enrolls the individual handbook owner into the Food and Drug Association along with a discounted price for the new updated regulations mailed directly to the association Member's address.

Examples of similar Member Based Associations:

FDA could be the single premier Association for the Health Care and Biopharmaceutical industry for Professionals and Consumers.

A world Regulatory and Quality Driven Dominated Association.

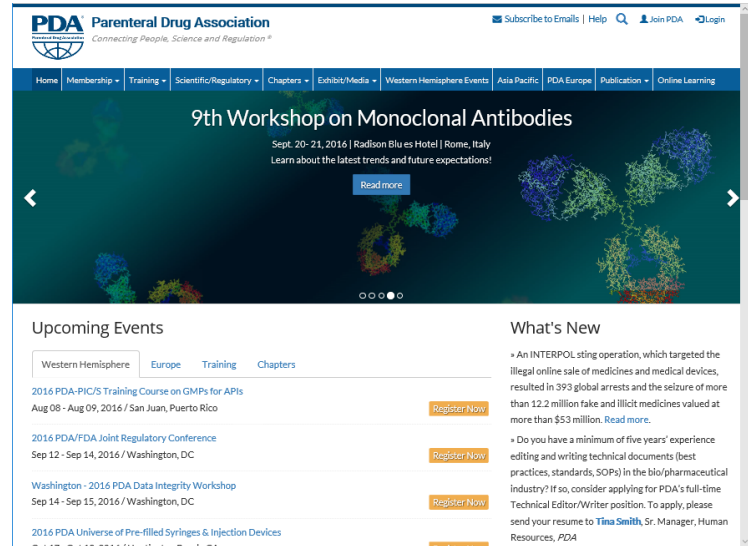
Associations such as, the ASQ, American Society for Quality, ISPE, International Society of Professional Engineers, PDA, The Parenteral Drug Association, etc. have an extensive paid membership pertaining to specific industry. Each one of these associations have thousands of members world-wide, who need and require targeted information immediately.



ASQ Currently has 80,000 members x \$159.00 Annual Subscription = \$12,720,000 Annually

ISPE Currently has 20,000 members x \$284.00 Annual Subscription = \$5,680,000 Annually

See Attachment C – ASQ Media Kit



FDA.COM for Industry Revenue Potential for Subscriptions

- Food and Drug Association – For Industry Professionals - \$60 - \$120 Annual Subscription
 - \$200.00 x 10,000 annual subscribers = \$2,000,000
 - **\$200.00 x 50,000 annual subscribers = \$10,000,000 – 5 Year Target**
 - \$200.00 x 100,000 annual subscribers = \$20,000,000
 - \$200.00 x 1,000,000 annual subscribers = \$200,000,000

Food and Drug Assistance Association – for Consumers - Condition States

- Acne
- ADD and ADHD
- AIDS/HIV
- Allergies
- Alzheimer's
- Arthritis
- Asthma
- Autism
- Back Pain
- Birth Control
- Cancer - Breast
- Cancer - Prostate
- Cholesterol
- Common Cold | Flu
- Crohn's & Colitis
- Dental Health
- Diabetes
- Diet & Nutrition
- Ear Disorders
- Epilepsy
- Erectile Dysfunction
- Glaucoma
- Hair Loss
- Headache | Migraine
- Heartburn
- Heart Attacks
- Hepatitis
- Hemorrhoids
- Kidney
- Lyme Disease
- Men's Health
- MRSA
- Multiple Sclerosis
- Osteoporosis
- Parkinson's
- SARS
- SIDS
- Skin Care
- Sleep Disorders
- Smoking
- Snoring
- Stress | Depression
- Stroke
- Vitamins
- Weight Control

Additional States added

Ties into www.yourfda.com website memberships.

Ties into www.fdamd.com website.

Member Benefits for Consumers:

- Targeted Emails specific to each Member's Condition State interest along with;
- Targeted RSS Feeds specific to each Member's interest
- Access to Webinars and Seminars specific to each Member's interest
- Access to FDA Agency, Medical Journals and Scientific reports specific to each Member's interest and Condition State
- Live access to FDA Meetings and Seminars pertaining to Member's interest
- Clinical Trials, Enrolments, Reviews and New Product Data
- Access to Doctors, Nurses and Medical Professionals Live Portals and Discussion Groups
- Access to Drug Information and Brochures
- Access to Medical Device Information
- Health and Lifestyle Information Portal

For a low annual membership cost, users can gain access to detailed information pertaining primarily to their own specific Condition State.

FDA.COM for Consumers Revenue Potential for Subscriptions

Membership fees could vary based upon Membership preferences.

- Food and Drug Assistance – For Consumers - \$29 – \$59 Annual Subscription
 - \$29.00 x 10,000 annual subscribers = \$290,000
 - **\$29.00 x 50,000 annual subscribers = \$1,450,000 – 3 Year Target**
 - \$29.00 x 100,000 annual subscribers = \$2,900,000
 - \$29.00 x 1,000,000 annual subscribers = \$29,000,000

Manpower Required

- Software Developers – HTML, Joomla, Database Development
- Content Subject Matter Experts (SMEs)
- Medical Professionals and Content Subject Matter Experts (SMEs)
- Graphic Designers
- Sales and Marketing
- Database Administrator (DBA)

Equipment / Resources Required

- Dedicated Computer Server and Rack Space
- Backup Redundant Server
- Subscriptions to resources