Regulatory Considerations of Brand Owners in a Manufacturing Partnership

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Regulatory Considerations of Brand Owners in a Manufacturing Partnership

“20/20” cGMP Vision:

The Key to Sustainable Success for the Future
Regulatory Considerations of Brand Owners in a Manufacturing Partnership

Who is a “Brand Owner”:

■ OWN LABEL DISTRIBUTORS (OLDs)

■ PRIVATE LABEL DISTRIBUTORS (PLDs)

■ E-COMMERCE DISTRIBUTORS (e.g. Virtual companies) (ECDs)
What defines you as an OLD / PLD or ECD?

- Outsourcing your product to another firm for:
  - Manufacturing
  - Packaging and/or Labeling (i.e. to a co-Packer)
  - Warehousing (Holding) and Distribution (into commerce)
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OUTLOOK
For the Own Label Distributor Industry…..

What does the future hold?
“20/20” cGMP Vision: The Key to Sustainable Success for the Future

Brief GMP History

■ 1938: The Federal Food, Drug, and Cosmetic Act
Among other provisions, the law authorized the FDA to demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections. [Link to FDA]

■ 1994: DSHEA (Dietary Supplement Health & Education Act)
Broadened Historical Definition of Dietary Supplements
Provided for structure/function and health claims
Congress gave FDA express authority to issue regulations establishing good manufacturing practices (GMP)
[Link to DSHEA]

Requires certain activities in manufacturing, packaging, labeling and holding of dietary supplements to ensure that a dietary supplement contains what it is labeled to contain and is not contaminated with harmful or undesirable substances such as pesticides, heavy metals, or other impurities.
Requires certain activities that will ensure the identity, purity, quality, strength, and composition of dietary supplements.
[Link to CFR Part 111]
Who is Subject to 21 CFR Part 111?

Current Good Manufacturing Practice (cGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

Applicable to:
- Manufacturers
- Packagers
- Labelers
- Holding Facilities (Warehouses)
- 3rd Party Logistic Distributors (3PLs)
- OLDs/PLDs/ECDs

Not Applicable for:
- Retail Establishments (Vitamin, Supplement stores)
- Dietary Ingredient Suppliers (i.e. Raw Materials)
- Component Suppliers (i.e. Caps, Bottles)
21 CFR 111 Subparts

- A – General Provisions
- B – Personnel
- C – Physical Plant and Grounds
- D – Equipment and Utensils
- E – Requirement to Establish a Production and Process Control System
- F – Quality Control
- G – Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement
- H – Master Manufacturing Record
- I – Batch Production Record
- J – Laboratory Operations
- K – Manufacturing Operations
- L – Packaging and Labeling Operations
- M – Holding and Distributing
- N – Returned Dietary Supplements
- O – Product Complaints
- P – Records and Recordkeeping
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OTHER STATUTARY PROVISIONS

- 21 CFR 190, New Dietary Ingredient (NDI) Notification
- 21 CFR 11, Electronic Records; Electronic Signatures
- Dietary Supplement and Nonprescription Drug Consumer Protection Act (2006) – Serious Adverse Event Reporting (SAER)
- FOOD SAFETY MODERNIZATION ACT (FSMA) (2011)
  - Certain FSMA Rules; FSVP (Foreign Supplier verification Program) apply.
- 21 CFR 117, Current Good Manufacturing Practice (cGMP) and Hazard Analysis and Risk-Based Preventative Controls for Human Food
2011 FOOD SAFETY MODERNIZATION ACT (FSMA)  
(As it relates to Finished Dietary Supplement Products)

“A foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States has to register with FDA under section 415 of the FD&C Act and is subject to the requirements. Dietary supplements are “food” as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act). In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States has to register with FDA under section 415 of the FD&C Act and is subject to the requirements related to preventive controls of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule, unless subject to an exemption. An exemption for dietary supplements is provided in 21 CFR section 117.5(e) which states that subparts C (hazard analysis and preventive controls requirements) and G (supply-chain program requirements) of 21 CFR part 117 do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of 21 CFR part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the FD&C Act (21 USC section 379aa-1) (Serious Adverse Event Reporting for Dietary Supplements).”
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What are OLD’s cGMP Responsibilities?

[Total] Compliance with 21 CFR 111

- Correct Interpretation
- Clear Understanding
- Proper Development
- Effective Implementation
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Sharpening the Focus: 4 Key Steps

Hmm.... I can see clearly now.
Know and Understand the Applicable Regulations

- Qualify Contract Providers (CPs) who are an extension of OLDs
  - Co-Manufacturers; Co-Packagers; Warehouses (3PLs); Labs
- Take Ownership of the Processes and Controls
- Commit to Compliance and Oversight
- Be Accountable and Responsible for Adherence

FDA says:
“You must implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.” (21 CFR 111.55)
2. Establish Robust Quality Systems

- Establish applicable and effective SOPs for your operation
- Ensure to have Qualified, Experienced and Trained Staff
- Quality Assurance is key to monitoring contract providers (e.g. CMs)
  - Quality (Assurance/Control) Reviews, Approves, Releases

FDA says:
“Quality Control personnel must ensure that your manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.”
(21 CFR 111.105)
Key 3 - Avoid “Blind Spots” and “Common” Mistakes

■ The Contract MFR (CM) is known for years and there is no Quality Agreement (recommended)

■ Expectation of CMs ‘age old’ turnkey product delivery - “Make ➡️ Fill ➡️ Ship”

■ Batch Records (BPR)/Packaging Records (PR) not requested and reviewed for product release

■ Finished Product specifications not qualified through testing against CM’s Certificate of Analysis

■ CMs not qualified; No Onsite Audits performed (important to “Inspect what you expect”)
# The Top Three FDA Observational Citations

## FDA 2018 Fiscal Year Inspectional Observation Data

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<th>Citation Program Area</th>
<th>Cite Id</th>
<th>Reference Number</th>
<th>Short Description</th>
<th>Long Description</th>
<th>Frequency</th>
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<td>15839</td>
<td>21 CFR 111.70(e)</td>
<td>Specifications - identity, purity, strength, composition</td>
<td>You did not establish product specifications for the [identity] [purity] [strength] [composition] of the finished dietary supplement. Specifically, ***</td>
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<td>21 CFR 111.103</td>
<td>Written procedures - quality control operations</td>
<td>You did not [establish] [follow] written procedures for quality control operations. Specifically, ***</td>
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<td>Foods</td>
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<td>21 CFR 111.75(a)(1)(i)</td>
<td>Component - verify identity, dietary ingredient</td>
<td>You did not conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use. Specifically, ***</td>
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# Earlier FDA Observational Citations

**FDA Fiscal Year 2010 – 2017 Inspectional Observation Data**

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<td>21 CFR 111.553</td>
<td>Product Complaints</td>
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<td>21 CFR 111.453</td>
<td>Holding &amp; Distribution</td>
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<td><strong>Total Observations</strong></td>
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Data obtained from EAS Consulting Group

- **Unaddressed Inspectional Observations (Form 483)** by the FDA result in **Warning Letters**
- **Warning Letters** that are not responded to with repeat violations, result in **Injunctions**
FDA Enforcement

■ Inspectional Observation (FDA Form 483)
A written response by the firm to the FDA is expected within 15 business days.

▪ Good Response: “it appears you have addressed all observations, the Agency will assess during the next FDA inspection”
▪ Deficient Response: “We have reviewed your response letter, dated MM DD YYYY, and determined your response to be inadequate.”

■ Warning Letter
▪ Had opportunity to respond to the FDA 483(s); but disregarded responding within the 15 business days (or at all)
  (Note: Can request an extension from the (District) Agency and it is often given).
▪ The FDA Form 483 response is inadequate and does not address the issues observed by the Investigator

■ Consent Decree (Permanent Injunction)
▪ Commonly Follows “Inadequate” Response to a Warning Letter
▪ Issued by Federal Court at FDA’s Request
▪ Company Consents to Content of Decree
▪ Takes Effect Immediately
▪ Costly; Company may never recover
“Although a firm may contract out certain dietary supplement manufacturing, packaging, and/or labeling operations, **it cannot contract out its ultimate responsibility** to ensure that the dietary supplement it places into commerce (or causes to be placed into commerce) is not adulterated for failure to comply with dietary supplement CGMP requirements [see United States v. Dotterweich, 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the Act by anyone who has “a responsible share in the furtherance of the transaction which the statute outlaws”); United States v. Park, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that “agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act” can be held accountable for violations of the Act)]. In particular, the Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce a dietary supplement that is adulterated under section 402(g) for failure to comply with dietary supplement CGMP requirements [see 21 U.S.C. §§ 342(g) and 331(a)]. Thus, a firm that contracts with other firms to conduct certain dietary supplement manufacturing, packaging, and labeling operations for it is responsible for ensuring that the product is not adulterated for failure to comply with dietary supplement CGMP requirements, regardless of who actually performs the dietary supplement CGMP operations.”
FDA Injunction
(An OLD did not Audit or manage the Process and Controls of their Contract Manufacturer)

July 1, 2014 – Injunction – Mira Health (New York)

U.S. Files Complaint and Consent Decree Against Mira Health and Senior Officers

“Mira gained national attention in July 2013 when Purity First Health Ltd, a company that sold dietary supplements manufactured by Mira, became the subject of an FDA recall. Anabolic steroids were found to be present in the Healthy Life Chemistry By Purity B-50 dietary supplement. At the time of the recall, 29 illnesses and one hospitalization had been documented.”

Candice Tripp, Purity Life Owner; Eastport NY (2013) [Own Label Distributor]
https://www.academia.edu/6589538/Healthy_Life_Chemistry_By_Purity_First_B-50_FDA_Health_Risk
FDA Warning Letter

August 10, 2016 – Warning Letter to Perfect Source Natural Products Inc. (California)
(An OLD whose contract manufacturer did not provide scientifically valid verification of their dietary supplement)

“You state that finished product testing for the Perfect Solution products is conducted by your contract manufacturer. However, the testing records you provide do not show that the contract manufacturer verified, for a subset of finished dietary supplement batches identified through a sound statistical sampling plan (or for every finished batch), that the finished batch of the dietary supplement meets product specifications for identity, purity, strength and composition of the finished batch of the dietary supplement, as required by 21 CFR 111.75(c)………

Your response states that it is not possible to utilize a scientifically valid test method to test and verify every specification set in your multi-ingredient dietary supplements………

Per 21 CFR 111.75(d)(1) and (2), a manufacturer may exempt a product specification from the verification requirements if it determines that the selected specifications under paragraph (c)(1) are not able to verify the product meets the exempted specification and there is no scientifically valid method for testing or examining the exempted product specification at the finished batch stage. If the manufacturer exempts certain finished product specifications from testing, it must document why, for example, any component and in-process testing, examination, or monitoring, and any other information, will ensure that such exempted product specification is met without verification through periodic testing of the finished batch; and the quality control personnel must review and approve this documentation.

Your response states that by confirming the product’s identity, the purity, strength, and composition is also confirmed, without any tests on the finished product. However, you fail to account for factors that can impact the strength and composition of each of the specifications in your finished products such as mixing, uniformity, product loss, etc. You are basing your finished product specifications being met for strength on achieving 100% yield and mixing uniformity; however your response did not include other test results or information from the manufacturer conducting the testing that demonstrates your products meet all your finished product specifications.
FDA Warning Letter

February 7, 2018 – Warning Letter Reishi D. International, Inc. (California)

“You must also provide written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements, as required by 21 CFR 111.140(b)(2). Specifically, during the inspection you did not provide documentation of the approval for release of your dietary supplements by your quality control personnel.”
FDA Warning Letter

September 12, 2019 – Warning Letter [Redacted] (New York)

“You failed to establish product specifications for the identity and purity of the finished batch of dietary supplement that you manufacture, as required by 21 CFR 111.70(e). For example, your product specification in the master manufacturing records for (b)(4) and (b)(4) do not include specifications for identity and purity.”
FDA Warning Letter

June 20, 2019 – Warning Letter to [Redacted]
(Utah)
(A contract manufacturer held equally responsible for OLD product compliance)

During the inspection, you explained to our investigator that you are responsible for the content of the Supplement Facts label only on the products contract manufactured by your firm. To the extent that your firm labels products on behalf of another firm that releases for distribution that product under their firm’s name, your firm nevertheless has an obligation to know whether that product’s label and labeling is in conformance with the Act (see United States v. Dotterweich, 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the Act by anyone who has “a responsible share in the furtherance of the transaction which the statute outlaws”); United States v. Park, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that “agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act” can be held accountable for violations of the Act). The Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce a dietary supplement that is misbranded under section 403 of the Act (see 21 U.S.C. 342(g) and 331(a)).
4 - Supply-Chain Transparency and Specifications

■ Supply Chain Management - Review and Monitor CMs’
  - Raw Material Certificates of Analyses (CoAs) and Supplier Qualification
  - In-Process
  - Finished Product

■ Develop credible, scientifically sound Product Specifications:
  - Raw Material
  - In-Process
  - Finished Product

■ No “By Input” Test Method designation

■ Label Specifications (21 CFR 101.9; 101.36)

■ Component Specifications (e.g. caps, bottles)

FDA says:
“(e) For each dietary supplement that you manufacture you must establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement. (21 CFR 111.75(e))”
Supply-Chain Flow

Raw Material Supplier → Manufacturer (and Packager) → Packager → Warehouse (Holding) → Distribution

Own Label Distributor

Direct to Consumer

Direct to Retailer
ESTABLISH, TEST AND VERIFY SPECIFICATIONS
(21 CFR 111 Subpart E (111.70 – 111.77)

SupplySide West
According to the current analysis of Reports and Data, the global Dietary Supplements Market was valued at USD 124.8 Billion in 2018 and is expected to reach USD 210.3 Billion by year 2026, at a CAGR of 6.4%.

NEW YORK, March 25, 2019 (GLOBE NEWSWIRE)
“20/20” cGMP Vision: The Key to Sustainable Success for the Future

OUTLOOK

CLEAR FOCUS on COMPLIANCE ...

LOOKS GOOD!

What does the future hold NOW?
“20/20” cGMP Vision: The Key to Sustainable Success for the Future

TAKE AWAYS

■ Know and Understand the Applicable Regulations
■ Focus on Establishing Effective Quality Systems
■ Develop Scientifically Sound Specifications
■ Avoid Blind Spots
■ Audit and Monitor the Supply Chain
■ Clear cGMP Focus, Clear and Good Future!!

SupplySide WEST
References:

- Slide # 10
  https://www.fda.gov/media/119823/download

- Slide # 16
  https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations

- Slide # 19

- Slide # 21

- Slide # 22
References:

► Slide # 23

► Slide # 24

► Slide # 28
Questions?
More Information?

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Contract Manufacturing Roundtable:  
How to Foster a Successful Partnership  
October 19, 2019

**Contract Manufacturing Partnerships**  
Ensuring Both Parties Have a Successful, Mutually Beneficial Relationship

Kurt C Schneider  
President, Tech Bridge West
Today’s Agenda

- Survey Question #1

- Part One: Due Diligence
  - The Brand Owner
  - The Contract Manufacturer
  - The Quality Audit
  - The Supplier Pre-Approval Questionnaire

- Part Two: What the Brand Owner Needs to Know About Their Product

- Survey Question #2

- Part Three: On To the First Production Run?
  - The Quality Agreement

- Part Four: That’s All, Right?
  - Spec Drift and Quality Reviews

- Survey Question #3

- Part Five: A Final Word to All Vested Parties
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October 19, 2019

Survey Question #1

Contract Manufacturing Partnerships: Ensuring Both Parties Have a Successful, Mutually Beneficial Relationship
PART ONE: DUE DILIGENCE

- **Responsibilities of:**
  - The Brand Owner
    - Their Business
    - Their Operation
    - Their Quality/Compliance Programs
    - Their Reviews
    - Your Gut Feel
  - The Contract Manufacturer
    - Their Business
    - Their Operation
    - Their Quality/Compliance Programs
    - Their Reviews
    - Your Gut Feel

- **Tools you can use**
  - The Supplier Pre-Approval Questionnaire
  - The Quality Audit
## Contract Manufacturing Roundtable:
How to Foster a Successful Partnership
October 19, 2019

### Part One: Due Diligence

#### Supplier Pre-Approval Questionnaire

Please complete the following information and return to Tech Bridge West as soon as possible. All details provided to us will be treated as confidential and only used to support the approved supplier requirements of our feed safety program.

**Administrative Information**

- Corporate Name: ____________________________
- Division Name: ____________________________
- Company Website: __________________________
- Facility Address: ____________________________
- Mailing Address: ____________________________

**Quality Contact Information**

- Name and Title: ____________________________
- Telephone Number: _________________________
- Fax Number: ______________________________
- Email: ________________________

**Description of Product(s) to Be Supplied**

- Product Name(s): ____________________________
- Description: ____________________________
- Other products produced in the facility: ____________________________

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**Management Commitment and Responsibility**

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<td>A written management policy?</td>
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<td>A written management quality assurance policy statement?</td>
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<tr>
<td>A written management environmental policy?</td>
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<tr>
<td>Integrated quality system?</td>
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**Quality and Food Safety Management System**

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<td>A quality and food safety manual?</td>
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<tr>
<td>A written procedure for document control?</td>
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<tr>
<td>A written procedure for keeping and maintaining records?</td>
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**Personnel and Training**

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<td>Written job descriptions for all employees?</td>
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<td>A current training program?</td>
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<td>An additional invoice?</td>
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**Infrastructure**

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<td>A documented preventative maintenance program?</td>
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<td>A documented pest management program?</td>
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<td>100% coverage for all pesticides and herbicides used or stored on site?</td>
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<td>Written bypass procedures auditing methods, equipment, and areas for inspection?</td>
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**Supplier Pre-Approval Questionnaire**

This form must be completed by the supplier before pre-approval can be granted.

I hereby declare, to the best of my knowledge, the answers within this questionnaire are true and accurate. I understand this information will be used in the Tech Bridge West supplier evaluation process. I understand pre-approval does not grant full approval and further actions will be taken to complete the supplier approval process.

**Form Completed By:**

- Name: ____________________________
- Phone: ____________________________
- Position: _________________________
- Date: ____________________________

**Signature:** ________________________

---

For Tech Bridge West internal use only:

**Supplier Pre-Approval**

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**Updated: 3-2-17**

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**SupplySide West**
## Contract Manufacturing Partnerships: Ensuring Both Parties Have a Successful, Mutually Beneficial Relationship

### Part One: Due Diligence

#### Quality Audit

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<th>Audit Findings</th>
<th>Action</th>
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<td>2. Process Overview</td>
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<td>3. Equipment</td>
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<td>5. Cleaning</td>
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<td>6. Maintenance</td>
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#### Contract Manufacturer Quality Audit

- **Product:**
  - **Quality Control:**
    - Final product label
    - Final product dating
  - **Personnel:**
    - Personnel training
  - **Equipment:**
    - Equipment maintenance
  - **Cleaning:**
    - Cleaning procedures
  - **Maintenance:**
    - Maintenance procedures

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**Conclusion:**

A successful contract manufacturing partnership requires trust, communication, and mutual understanding. By implementing thorough due diligence and regular quality audits, both parties can ensure that the manufacturing process meets high standards and expectations.
Contract Manufacturing Roundtable: How to Foster a Successful Partnership
October 19, 2019

Part Two: What the Brand Owner Needs to Know About Their Product

- Annual Volume/Minimum Volume On-Hand
- Lead Times Required

- Formula
- Specifications
  - Raw Material
  - Finished Product
- Gold Standard

- Process
  - In-Process Specifications
  - Environmental Conditions
- Packaging Form/Specifications
- Testing Requirements/Methods
- Stability/Shelf Life
- Retains Requirements

...........Just to Name a Few.............
Survey Question #2
PART THREE: ON TO THE FIRST PRODUCTION RUN?

NOT SO FAST!!!!!!

• STEPS TO CONSIDER:
  • WITNESS A TRIAL RUN
    • BENCHTOP
    • PILOT PLANT
    • PRODUCTION SCALE
  • TEST THE LIMITS OF YOUR PRODUCT
    • STRESS THE ENDPOINTS OF YOUR SPECIFICATIONS
    • SET CONTROL LIMITS
    • REVISE SPECIFICATIONS TO MATCH CAPABILITIES IF POSSIBLE
  • ENSURE EVERYONE UNDERSTANDS YOUR DEFINITION OF QUALITY
  • BE THERE FOR THE FIRST PRODUCTION RUN

• TOOLS YOU CAN USE
  • CONTROL CHARTS
  • THE QUALITY AGREEMENT
Part Three: On to the First Production Run?

Control Charts
PART THREE: ON TO THE FIRST PRODUCTION RUN?

THE QUALITY AGREEMENT

• What is a Quality Agreement?
  • A formal agreement signed by both parties
  • Sets the manufacturing standard
  • Explains who owns what and when
  • Compliments the manufacturing and supply agreement

• Why is it Vital to Have?
  • Formalizes what has been agreed upon
  • Links to the correct 21CFR standards
  • Provides all documents required
  • Functions as ‘You’ when you aren’t there
**Contract Manufacturing Partnerships:** Ensuring Both Parties Have a Successful, Mutually Beneficial Relationship

**Part Three: On to the First Production Run? The Quality Agreement**

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How to Foster a Successful Partnership

October 19, 2019

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(Your Company Name)
Contract Manufacturer Quality Agreement

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**3. Right to audit**

**Contract Manufacturer Name** shall have the right to audit **Your Company Name** at any time, upon prior notice, to verify compliance with this Agreement, including the whole or a representative part of the manufacturing, packaging, testing, and storage facilities related to the manufacture of **PRODUCT**. The frequency of the audits shall be stated in the Agreement. Your Company Name shall have the right to be accompanied by its auditors during the audit of **PRODUCT** to verify the quality of each step in the manufacturing process.

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**5. Non-Conforming**

**Contract Manufacturer Name** shall have the right to return to **Your Company Name** any non-conforming or substandard **PRODUCT** at your cost. **Your Company Name** shall have the right to inspect all **PRODUCT** prior to release and if found non-conforming, return it to **Contract Manufacturer Name**.

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**6. Termination**

**CONTRACT MANUFACTURER NAME** and **Your Company Name** may agree to terminate this Agreement at any time, upon prior notice to the other party. **Your Company Name** shall have the right to terminate this Agreement if **CONTRACT MANUFACTURER NAME** breaches any of the provisions of this Agreement. **CONTRACT MANUFACTURER NAME** shall have the right to terminate this Agreement if **Your Company Name** breaches any of the provisions of this Agreement.

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**Your Company Name**

**CONTRACT MANUFACTURER NAME** Contract Manufacturer Quality Agreement

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**[Company Name]**

Date: ____________________

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**Contract Manufacturer Name**

Date: ____________________

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**Your Company Name**

Date: ____________________

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**Summary:** By signing this contract, both parties agree to the terms and conditions outlined in the Quality Agreement, ensuring a successful, mutually beneficial relationship.
**PART FOUR: THAT’S ALL, RIGHT?**

**NOPE!**

- **Spec Drift**
  - Follows the theory of Entropy
  - The Process, unless monitored and controlled, will run at the settings most economical and advantageous for the contract manufacturer
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PART FOUR: THAT’S ALL, RIGHT?

HOW TO AVOID SPEC DRIFT?

• QUALITY REVIEWS
  • CONTRACT MANUFACTURER PULLS PRODUCTION SAMPLES
    ON A REGULAR BASIS
    • EVERY LOT FOR COMPLIANCE
    • HOLDS IN CONTROLLED STORAGE
  
  • PERIODICALLY THE BRAND OWNER REVIEWS THESE
    SAMPLES
    • QUARTERLY IF PRODUCING MORE THAN 6 LOTS
    • SEMI-ANNUALLY IF PRODUCING 1-5 LOTS
PART FOUR: THAT’S ALL, RIGHT?

PRODUCT REVIEW – HOT COCOA
Part Four: That’s All, Right?

Survey Question #3
Are These Both Still Acceptable?
PART FIVE: A FINAL WORD TO ALL VESTED PARTIES

COMMUNICATION!!!!!!

- PRODUCT REVIEWS
- MANAGEMENT REVIEWS
- SPECIFICATION ADJUSTMENTS
- RAW MATERIAL ADJUSTMENTS/New Supplier

REGULAR COMMUNICATION BETWEEN THE BRAND OWNER AND CONTRACT MANUFACTURER IS THE ONLY WAY TO ENSURE BOTH PARTIES GET WHAT THEY NEED EVERY TIME
THANK YOU!

**Contract Manufacturing Partnerships**

*Ensuring both parties have a successful, mutually beneficial relationship*

Kurt C Schneider
President, Tech Bridge West