# Supplier Quality Agreements

Dan O'Leary CBA, CQA, CQE, CRE, SSBB, CIRM
President
Ombu Enterprises, LLC
Dan@OmbuEnterprises.com
www.OmbuEnterprises.com
603-209-0600

# Speaker Biography

- Dan O'Leary
  - Dan O'Leary is President of Ombu Enterprises, LLC, an education, training, and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management.
  - Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs.
  - He holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.
- Ombu Enterprises, LLC
  - Ombu works with small manufacturing companies, offering training and execution in Operational Excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

# Outline

- ISO 9001 Requirements for Purchasing
- Supplier Evaluation Tools
- ISO 9004 Model
- Supplier Quality Agreement
  - Administrative Elements
  - Compliance
  - Manufacturing
  - Documentation and Records
  - Storage and Shipment
  - Change Control
  - Non-Conformance, CAPA, and Complaints
  - Auditing
- Summary and Conclusions
- Questions

# Availability

- The following items are available to download from my web site

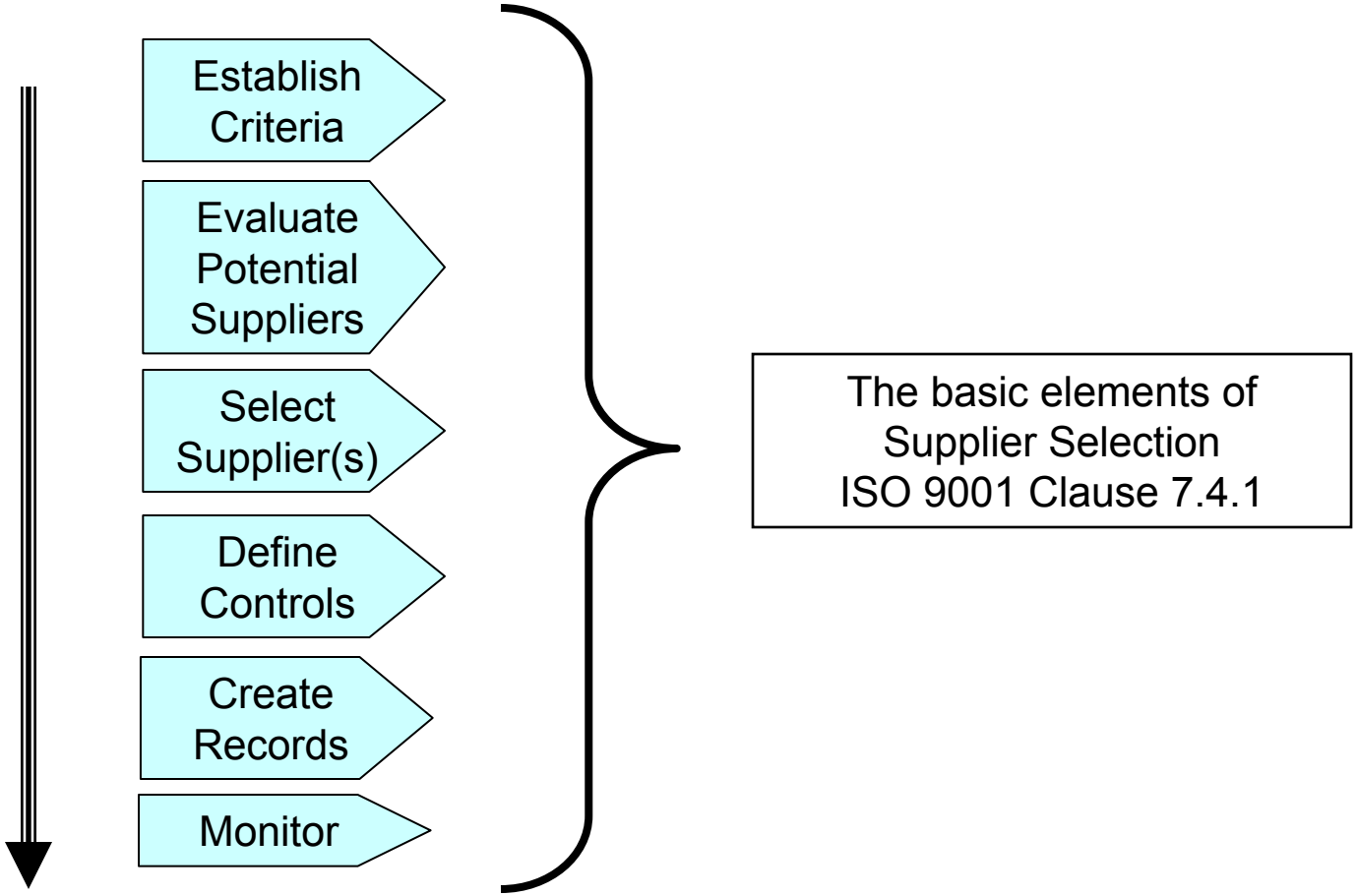
  www.OmbuEnterprises.com

- Click on Library
  - Look at Managing the Supply Chain
  - You will see today's slides and the template

# ISO 9001 Requirements for Purchasing (Clause 7.4)

Requirements
Evaluation
Selection
Supplier Agreements and Other Controls

# Supplier Selection – ISO 9001 Approach



# ISO 9001 – Purchasing Process

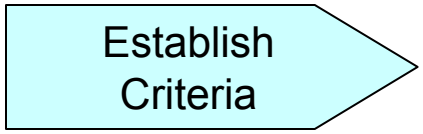
Purchasing Process

Requirement 7.4.1
The organization shall ensure that purchased product conforms to specified purchase requirements.

Discussion
There are two major points here:
- You have specified purchase requirements
- You have a method to verify conformity

In our example, you're a "purchasing" a process from a second party, i.e. somebody outside the scope of your QMS.

# Establish Criteria




Requirement 7.4.1
Criteria for selection, evaluation, and re-evaluation shall be established.

Discussion
- Establish the criteria for evaluation and selection before starting the process.
- Note that the criteria for re-evaluation are also included in this clause.

- In some cases, corporate policy may not give you an opportunity to develop independent selection criteria. However, the use of selection criteria is still important to the process.
- The evaluation criteria, is critical to establishing controls.

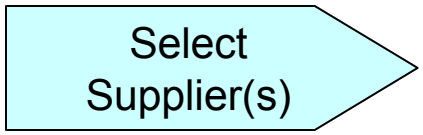
# Evaluate Potential Suppliers

Evaluate Potential Suppliers

Requirement 7.4.1
The organization shall evaluate … suppliers based on their ability to supply product in accordance with the organization's requirements.

Discussion
- Establish the criteria for evaluation and selection before starting the process.
- Product includes services, software, hardware, and processed materials
- Supplier includes both "monetary" and "non-monetary" transactions
- Suppliers can be totally independent or part of the same parent organization

# Select Suppliers




Requirement 7.4.1
The organization shall … select suppliers based on their ability to supply product in accordance with the organization's requirements.

Discussion
- The selection criteria are set in an earlier step.
- Potential suppliers are evaluated against the selection criteria.
- Select the supplier(s) that is the best match against the criteria.
- You may not have a supplier that fully matches the criteria, so you may need to exercise controls to help close the gap.

- If the supplier selection is dictated by corporate policy (part of the same parent organization), then the choice is easy
- You still need to maintain a record showing why you selected the supplier

# Define Controls

Define Controls

Requirement 7.4.1
The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

Discussion
- Controls can come from two sources:
  - Base Control Plan
  - Additional Control Plan
- The Final Control Plan consolidates the Base Control Plan and the Additional Control Plan
- Control is written in a risk based fashion, based on the effect of purchased product (including services) on the effect of the final product.

# Create Records


Requirement 7.4.1
Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

Discussion
- As always, maintain records.
- Actions resulting from the evaluation means that you might ask the supplier to perform additional tasks, develop new capabilities, *etc*.
- I could also include actions that you take as part of the control.

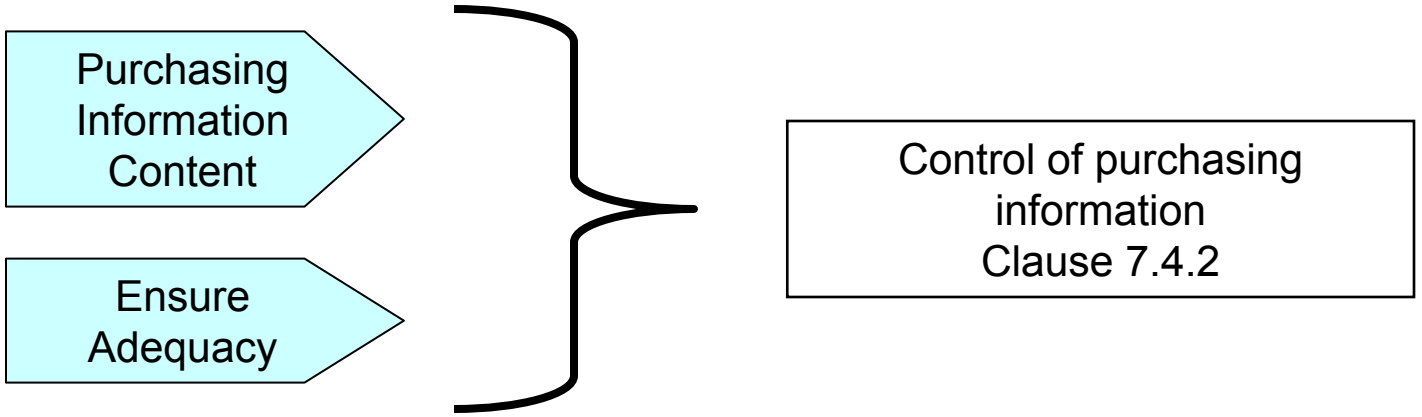
# Monitor

Monitor

Requirement 7.4.1
Criteria for selection, evaluation and re-evaluation shall be established.

Discussion
• We will implement monitoring through the Supplier Scorecard
• Monitoring also comes from Clause 4.1.e which says, “The organization shall … monitor, measure where applicable, and analyze these processes”

# ISO 9001 – Purchasing Information



# Purchasing Information Content

Purchasing Information Content

Requirement 7.4.2
Purchasing information shall describe the product to be purchased, including where appropriate
a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

Discussion
• The purchasing information defines the relationship between the supplier and customer. It should include requirements and specification about the product as well as additional information ranging from process qualification to the QMS system.
• We will divide the Final Control Plan into two components
    • The Supplier Agreement becomes part of the purchasing agreement
    • The Additional Activities are the things you will do to help exercise control

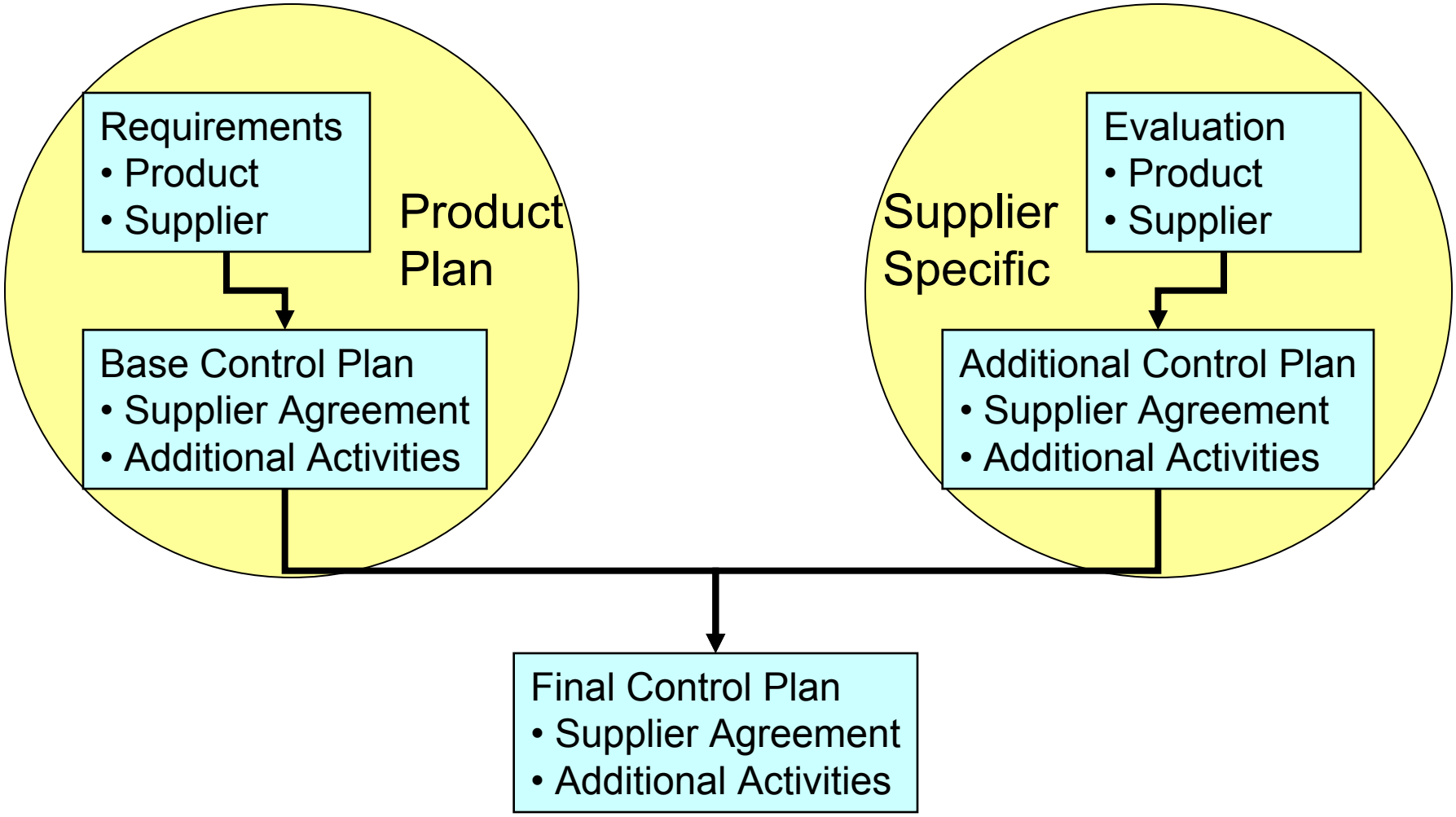
# Ensure Adequacy

Ensure Adequacy

Requirement 7.4.2
The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Discussion
• The standard doesn't stipulate document control, but it a best practice.
• Follow the established methods to review and approve documents, place them under document control, and ensure the correct revision is sent to the supplier.

# Overall Structure



# Supplier Evaluation Tools

# The Supplier Questionnaire

- Keep it simple
- Many companies prepare long questionnaires, but use the information to evaluate the supplier.
  - You may ask for the number of direct labor employees and the number of quality control employees.
  - Would you calculate the ration and use it to make a supplier selection decision?

# A Simple Questionnaire

- The handout contains a simple supplier questionnaire
- Basic criteria
  - Incorporated and carry risk insurance
  - Not in trouble with a regulatory agency
  - Experienced with the product or service you want to purchase

# A Simple Questionnaire

- Advanced criteria
  - Proven (good) reputation
  - Industry associations and memberships
  - Industry awards
  - Third-party assessments or certifications
  - Publications

# Supplier Evaluation

- Determine the criteria that you care about
- The handout has an evaluation form for the following areas
  - Capability
  - Capacity
  - Samples
  - Landed cost
  - Terms
  - Order to Receipt cycle
  - Financial Stability
  - Employee relations
  - Imported products
  - Regulatory Authority

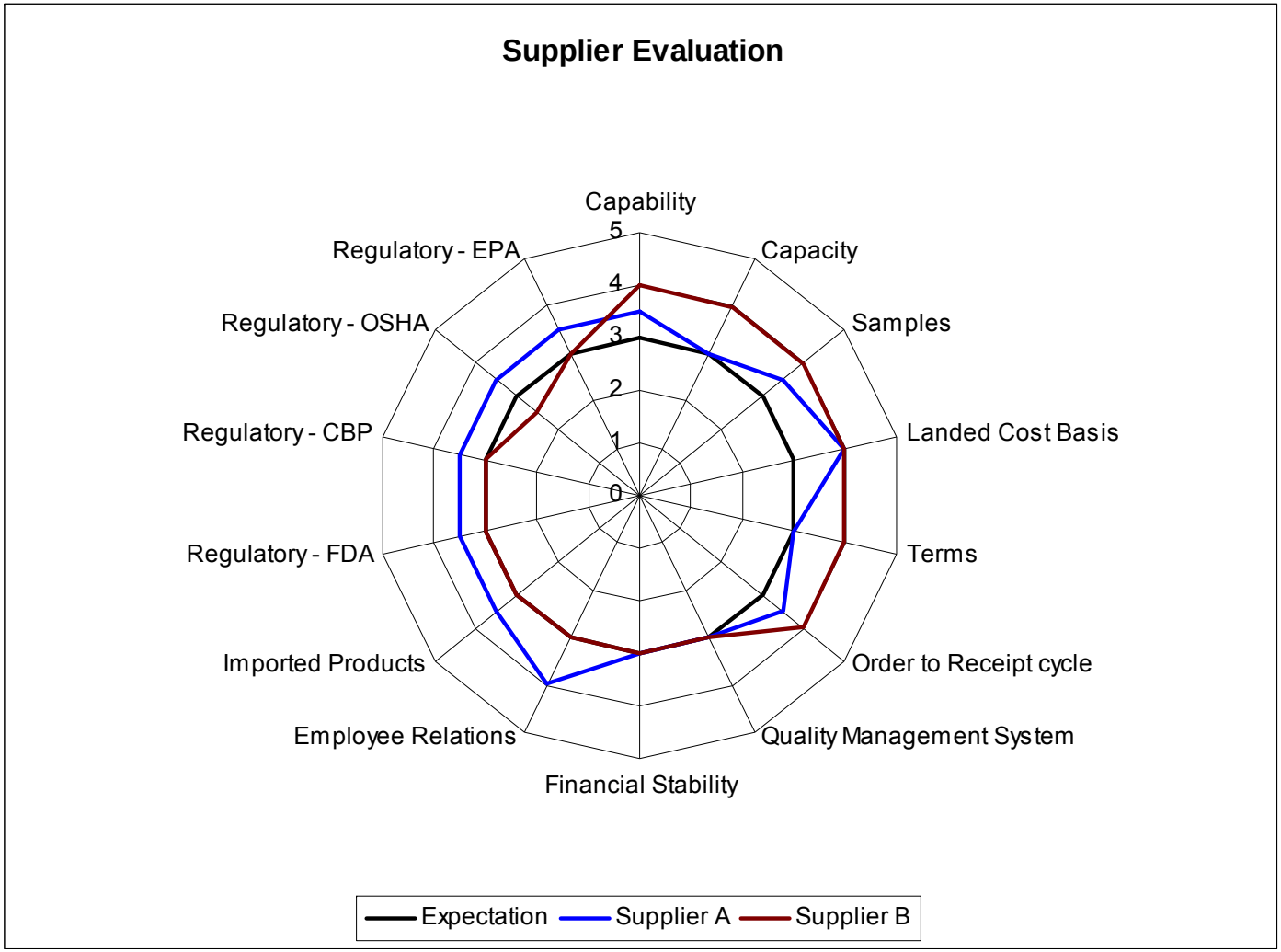
# Supplier Evaluation

- Determine your requirements
- Score each potential supplier on a scale of 1 to 5
- Your requirements are scored as 3
- Score each supplier
  - When the supplier satisfies your requirement, grade them 3
  - If they exceed your requirement, score them higher

# Supplier Evaluation

- You can just add up (or average) the scores, but this can miss important points.
  - A supplier with better than required terms may get a 4
  - A supplier with worse experience with OSHA may get a 2.
  - In addition or average, they will cancel out.
- A nice graphical approach is the radar chart.

# Radar Chart


Supplier Evaluation
Capability
Capacity
Samples
Landed Cost Basis
Terms
Order to Receipt cycle
Quality Management System
Financial Stability
Employee Relations
Imported Products
Regulatory - FDA
Regulatory - CBP
Regulatory - OSHA
Regulatory - EPA
5
4
3
2
1
0
Expectation
Supplier A
Supplier B

# ISO 9004 Model

# ISO 9004:2009

- This standard is part of the ISO 9000 family
- The title is, *Managing for the sustained success of an organization — A quality management approach*
- Two areas of interest to us are:
  - Suppliers and Partners
  - A Maturity Model applied to Suppliers and Partners

# Partners

- The organization should consider partnership as a specific form of relationship with suppliers, where suppliers can invest in and share the profits or losses of the organization's area of activity.

# Developing Partnerships

- When an organization is developing partnerships, the organization should give consideration to issues such as
  - the provision of information to partners, as appropriate, to maximize their contributions,
  - supporting partners, in terms of providing them with resources (such as information, knowledge, expertise, technology, processes, and shared training),
  - the sharing of profits and losses with partners, and
  - improving the performance of partners.

Source: ISO 9004, 6.4.1

# Selecting and Evaluating Suppliers and Partners

- Consider issues such as:
  - their contribution to the organization's activities and ability to create value for the organization and its interested parties
  - the potential for continually improving their capabilities,
  - the enhancement of its own capabilities that can be achieved through co-operation with the suppliers and partners, and
  - the risks associated in the relationships with the suppliers and partners.

Source: ISO 9004, 6.4.2

# Maturity Model

- ISO 9004:2005 contains a self-assessment maturity model
- The model uses five levels, from 1 to 5.
  - Level 1 is the base level
  - Level 5 is the best practice

# Supplier / Partner Maturity Model

| Maturity Level | | | | |
|---|---|---|---|---|
| Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
| Supplier communications are limited to tendering, order placement, or problem resolution | Processes are in place to communicate with, select, evaluate, re-evaluate, and rank suppliers | Suppliers and partners are identified in accordance with strategic needs and risks.<br><br>Processes for developing and managing the relationships with suppliers and partners exist. | Open communication of needs and strategies occurs with partners. | Data demonstrates that partners are engaged in and are contributing to the organizations, successes. |

Source: ISO 9004, Table A.4

# Supplier Quality Agreement

# When Do Need One?

- You should have a formal policy that defines the type of Product or Supplier that needs a Supplier Quality Agreement
  - Suppliers of critical components will qualify
  - Common material purchased in large quantities often qualify (Class A Items in inventory analysis)
  - Services that don't impact your product won't apply
    - The company that stripes your parking lot could be left out

# When Do Need One?

- You should the Base Supplier Agreement completed as part of requirements planning.
- When you have the short list of potential suppliers, send them a copy.
- Their response will be a major component in supplier evaluation

# The Supplier Agreement

- We will review a Supplier Agreement Template
- We don't make any claim of completeness
  - In fact, you will need to add specific information based on the supplier, product, and relationship.
- We don't include the additional activities you need as part of the control plan.
  - You may ask for a Certificate of Analysis in the Supplier Agreement
  - You may send a sample to an independent lab as part of your receiving acceptance activities

# Administrative Elements

Scope
Definitions
Products
QMS
Assignment

Parties
Referenced Documents
Sites
Third Parties

# Scope

- A good scope statement defines both what is “in” and what is “out”.
  - It defines the boundaries of the “box”
- The “ins” and “outs”
  - Commitment and cooperation are “in”
  - Forecasting, ordering, delivery, and pricing are “out”
  - Product specifications are “out”.
- The “outs” are covered in other places, just not here.

# Parties

- In this part there are two parties to the agreement, the Customer and the Supplier
  - The section on Parties identifies them by name, place of business, *etc*.
- Two issues will arise in subsequent sections
  - Where do the first two parties conduct business
  - What is the control of Third Parties who become involved

# Definitions

- Define the technical terms that appear in the agreement
- Use the definitions from standards when possible
  - ISO 9000:2005
  - ISO 9001:2008
  - ISO 9004:2009

# Referenced Documents

- List the documents by number, revision, and name to completely identify them.
- In the text you can use “shorthand” to refer to them
- Possible documents include:
  - ISO 9001:2008 Quality Management Systems – Requirements

# Products & Services

- List the products and services covered by the agreement
  - You could have more than agreement with the same supplier
  - Don’t define the specifications here or even list the revision of documents
    - There are better places to do this
    - You could create a maintenance problem, forgetting to update some impacted documents

# Sites Involved

- List the Suppliers and Customers site where work is performed
  - If the supplier makes the same product in multiple locations, you will want to know this
  - QMS registrations, such as 9001 are site specific
  - Don’t forget separate distribution centers
- This list will be very important if foreign locations are involved

# QMS Requirements

- The obvious choice is ISO 9001:2008
- Don't forget other standards that may be relevant in your industry
  - Automotive — ISO/TS 16949:2002
  - Education — IWA 2:2007
  - Energy — PC 242, ISO 50001
  - Food safety — ISO 22000:2005
  - Information security — ISO/IEC 27001:2005
  - Health care — IWA 1:2005
  - Local government — IWA 4:2005
  - Medical devices — ISO 13485:2003
  - Petroleum and gas — ISO 29001:2003

# Use of Third Parties

- We distinguish to kinds of third-party
  - Directed Procurement
    - The Customer directs the Supplier to use a certain supplier for a particular product or service
    - Examples:
      - The Customer has safety approval (UL, CSA, *etc*.) on a major electrical component that the Supplier will incorporate
      - The Customer has validated a sterilization processes that the Supplier will utilize
  - Supplier Selected
    - The Supplier has selected the Third Party
    - Examples:
      - The Supplier provides a power supply with an OEM line voltage transformer
      - The Supplier provides a sterile pack (using a contract sterilizer) the Customer incorporates in the final product

# Third Party – Directed Procurement

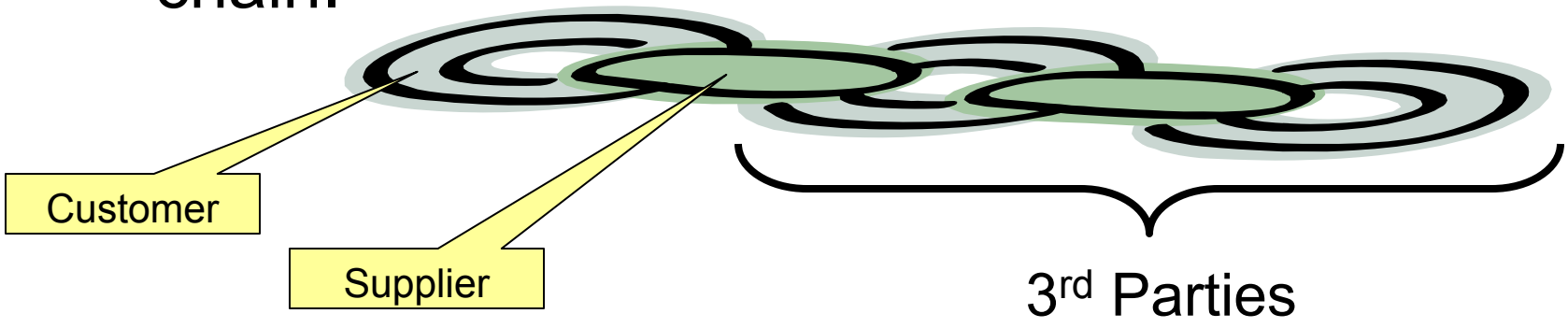
- The Customer has direct responsibility for the Third Party evaluation, selection, and performance.
  - The Customer may never write a PO to the Third Party
  - The Customer still needs to monitor and measure the Third Party Supplier's performance

# Third Party – Supplier Selected

- The Supplier has direct responsibility for the Third Party evaluation, selection, and performance.
  - If the Third Party Supplier provides an important product or service the Customer should know the Supplier's identity and qualifications
  - Knowing the identity of Third Party Suppliers outside the US can be critical.

# Third Party – The Generic View

- Take a broad view of Third Party
  - A Third Party Supplier is somebody in the supply chain who is neither the Customer nor the Supplier.
  - A Third Party Supplier could be in the fourth tier (starting with the customer) of the supply chain.



# Terms and Assignment

- These are typical clauses
  - Terms explain the length of the agreement and the provisions for renewal and termination
  - Assignment explains that neither party can assign its rights or obligations without approval of the other party

# Compliance

Specifications
Specification Changes
Activity by Regulators, Notified Bodies, or Certification Bodies
Third Party Quality Agreements

# Specifications

- The Customer defines the specifications for the Supplier.
- The Supplier undertakes to fulfill them
- The Actual Specifications
  - We don't define them here
  - We don't want to create a problem with excessive change control in this document
  - As part of evaluation of the Supplier you should have offered the specifications and gained agreement

# Specification Changes

- Both parties will agree to specifications changes before they go into effect
- Agreeing on the change is important
- Agreeing on the effectivity date can be critical!
  - Remember that the Apollo 13 accident was caused by failure to coordinate a change implementation from a 28 volt to a 65 volt power supply.

# Regulators

- Activity by Regulatory Authorities
  - In the US regulators could include the FDA, EPA, and OSHA (and corresponding state authorities)
  - Foreign suppliers have similar regulatory authorities
  - You want to be informed if you Supplier receives a formal visit
- Activity by Notified Bodies or Certification Bodies
  - Know when the surveillance activity is scheduled
  - Obtain copies of the reports and your Supplier's response.

# Third Party Quality Agreements

- The Supplier should have a Quality Agreement with the Third Party Suppliers
  - The Customer should have a Quality Agreement with Directed Procurement suppliers.
- The Customer should be able to get a copy from the Supplier on request.
  - If you get one, read it. Don't just file it for "paperwork compliance"

# Manufacturing, Packaging, and Labeling

Work Environment
Equipment
Monitoring And Measuring Equipment
Process Validation
Personnel
Automated Processes
Packaging Operations

# Tailoring the Template

- The Template rephrases and simplifies the requirements, but leaves the essentials in place
- Not every clause in the template will apply to all cases, so this is an area to expect a lot of tailoring

# Work Environment

- Based on ISO 9001 Clause 6.4
  - The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).
- Determine if the work environment is important to the product
- Implement appropriate controls keep them effective (good working order)
- Keep records of decisions, periodic maintenance, and performance checks

# Personnel

- Determine if contact between people and product could cause a problem
- If necessary, implement requirements for health, cleanliness, personal practices, and clothing.
- Keep records of decisions, periodic maintenance, and performance checks

# Equipment

- Based on ISO 9001 7.5.1.c
- Ensure manufacturing equipment is appropriately designed, constructed, placed, and installed.
- Establish maintenance, cleaning, and adjustment schedules
- Keep records of all these checks

# Automated Processes

- Validate the use of computer software that can impact product or service realization.
  - Not required by ISO 9001, but a best practice.
- Validation requires a protocol and a report
- Software change also requires a protocol and a report
- Keep records of all these activities

# Monitoring And Measuring Equipment

- Based on ISO 9001 7.6
- Establish schedules for calibration, adjustment, cleaning, and other maintenance
- Calibration standards should be traceable to national or international standards
- Keep records of all these activities

# Process Validation

- Based on ISO 9001 7.5.2
  - Requires process validation when the process output is not fully verified by inspection or test
  - Should assure a capable process ($C_{pk} \geq 1.33$)
- Validation requires a protocol and a report
- Process change also requires a protocol and a report
- Shipments from validated processes include process documentation:
  - The date the process was operated
  - The name of the operator
  - The identity of major equipment used
  - The identity and calibration recall date of test and measuring equipment used in the process
  - The setting of each input process parameter

# Packaging

- Pack and package the product
  - using the agreed methods or best practices
  - to protect the product from deterioration or damage during processing, storage, handling, and shipment.
- Keep records of the activities

# Documentation and Records

Device History Record

Record Retention

# Record Retention

- Define the record retention period
  - Make the record retention period the longest of all applicable rules
- For example:
  - the FDA regulation (for a medical device) may say 2 years
  - Sarbanes-Oxley (because these records may also be financial transactions) may require 7 years.

# Storage and Shipment

Storage

Shipment

# Storage

- Store product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects
- Retrieve product from stock using First In, First Out (FIFO) methodology.

# Shipping

- Ship products using agreed shipping methods to prevent the damage or deterioration of the product
- The Quality Agreement includes a table with the column headings:
  - Product
  - Packaging
  - Handling
  - Carrier
  - Reusable Container
- Reusable containers are an effective methods for both parties to cut costs
  - Be sure you define:
  - The party that purchases the initial stock of reusable containers
  - The party that replaces missing or damaged reusable containers
  - The party who owns the reusable containers at the end of the agreement

# Change Control

Change Requests

Deviations

Other Changes

# Change Requests

- Change requests are “permanent” changes
  - They will change the revision of the document, drawing, specification *etc*. to which they apply
- Change requests include:
  - the specific change
  - the reason for the change
  - the benefit derived from approving the request
  - the loss incurred from disapproving the request
  - the anticipated lead time before the change is reflected in the product
- The Customer must make a decision quickly and provide the rational for rejection

# Deviations

- Deviations are “temporary” changes
  - They do not change the revision of the document, drawing, specification *etc*. to which they apply
  - They expire after a certain time, number of parts, *etc*.

# Non-Conformance, CAPA, and Complaints

Disposition of Non-conforming Material
Corrective Action
Complaints
Medical Device Reports
Corrections and Removals

# Disposition of Non-conforming Material

- The Supplier segregates, investigates, and dispositions nonconforming material
- Dispositions
  - The Supplier can make rework and scrap dispositions
  - The Supplier needs Customer concurrence for a repair or concession disposition
- Nonconforming material dispositions are also used to update the Risk Management file

# Supplier Initiated Corrective Action

- The Supplier takes Corrective Action on Nonconforming Material, regardless of disposition
- Corrective Action includes the following steps:
  - Determining the cause(s) of nonconformity
  - Evaluate the need for action to ensure the nonconformity doesn't recur
  - Determine the action needed to prevent recurrence
  - Implement the action needed to prevent recurrence
  - Review the effectiveness of the corrective action

# Customer Initiated Corrective Action

- The Customer may initiate corrective action for the Supplier when the Customer identifies a nonconformity after receipt of the Supplier's product.
- Corrective Action includes the following steps:
  - Determining the cause(s) of nonconformity
  - Evaluate the need for action to ensure the nonconformity doesn't recur
  - Determine the action needed to prevent recurrence
  - Implement the action needed to prevent recurrence
  - Review the effectiveness of the corrective action
- Include timing for response in the agreement

# Supplier Received Complaints

- If the Supplier receives a compliant related to the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.
- The Customer enters the information into the complaint management system and makes an investigation decision

# Customer Received Complaints

- If the Customer receives a complaint it is entered into the Customer's Complaint Management System.
- The Customer reviews and evaluates the complaint to determine whether an investigation is necessary.
- If the Supplier's product is involved in the investigation, the Customer initiates a Corrective Action Request

# Audits

Customer Audits of Supplier Facilities

Customer Audit Findings

Auditing Third Party Suppliers

# Customer Audits of Supplier Facilities

- The Supplier allows the Customer (or authorized representative) to perform audits at the Supplier's facilities.
- Audits are conducted at mutually agreed dates and times.
- The Supplier and Customer agree to protect intellectual property

# Customer Audit Findings

- Customer audit findings are issued quickly (five working days)
- The Supplier prepares a plan for correction, cause, and corrective action quickly (thirty working days)

# Auditing Third Party Suppliers

- The Supplier allows the Customer (or authorized representative) to perform audits at Third Party facilities.
- Audits are conducted at mutually agreed dates and times.
- The Supplier, Third Party Supplier, and Customer agree to protect intellectual property

# Summary & Conclusions

# Summary

- Develop a Quality Agreement with major suppliers
- The Quality Agreement should start in the requirements determination phase.
- It will be tailored in the evaluation and selection phase.
- The Quality Agreement is part of the Supplier/Product control system

# Summary

- A major element in the agreement is the Quality Management System (QMS).
- Select the appropriate Quality Management Standard (ISO 9001)

# Conclusions

- Define your agreements with suppliers.
- Do not leave anything to “assumptions”
- The formal agreements are important, but do not let them override communication and collaboration.

# QUESTIONS