Certifying Body

User Guide

September 13th, 2017

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1. OVERVIEW

AUDITONE OVERVIEW

AuditOne delivers unprecedented value and process improvement to the supply chain. It provides focused execution via a singular standard agreed to by brand owners. Suppliers host one audit to the agreed standard which multiple, if not all, of their customers accept, thereby eliminating redundant audits. Suppliers share these audits securely with their customers via the AuditOne Platform, and which also provides instant qualification to any prospective customers. The AuditOne process applies throughout the supply chain providing unparalleled transparency.

AuditOne Platform

The platform was developed to cost effectively connect buyers, suppliers and service providers (such as certifying bodies) on a global scale, creating transparency and trust throughout the end-to-end supply chain. Like most popular business networking websites, organizations and individuals have the ability to connect to others seamlessly and easily on the AuditOne platform.

The AuditOne platform is a cloud-based application developed in conjunction with our technology partner, greenfence, and hosted by AWS (Amazon Web Services). It is secure, fast and highly scalable as additional brand owners, suppliers and certifying bodies are added.

By partnering with Amazon Web Services(AWS) and greenfence, AuditOne is being hosted by a global infrastructure specialist maintaining one of the largest, most-secure, cloud services environments in the industry. AWS boasts some of the highest security, up time, and data throughput metrics in the industry.

By using state-of-the-art cloud computing, an innovative and highly scalable architecture, AuditOne can deliver on its value proposition with confidence.

A brief overview video can be found here: https://youtu.be/INNeBQ5LM3c

Standards

Brand owners have agreed to singular standards for each category within the non-foods FMCG/CPG Industry for which they will accept third party audits in lieu of customer-specific audits. Approved certifying bodies (CBs) to conduct the audits can be found, here. AuditOne is currently rolling out standards for 5 categories. Other categories will be rolled out in the future.

AUDITOR GUIDANCE DOCUMENT
(June 4th, 2017-Version 4)

The Auditor Guidance Document was developed to convey the specific program requirements of the participating brand owners. The document reflects the brand owner expectations of the participating certification bodies. The CBs are acting as a proxy for the brand owner auditors, and as such are expected to follow these guidelines.

When there are changes in expectations, the document will be updated to reflect the changes, and participating CBs notified according to the AuditOne change control process.

The following guidance elements apply to all AuditOne audits:

1. The audits required for this program will be an in-depth audit, verifying the effectiveness of the quality systems being reviewed through objective evidence, plant floor examination at least 50% of the audit time, and employee interviews. Without sufficient objective evidence validating that the quality systems are performing as designed, the audit ***will not*** be approved by the participating brand owners.

2. The program is based upon an ***annual*** comprehensive audit to the standard required, the audit must be based upon objective evidence that the quality systems are operating as prescribed.

3. The audit required is an in-depth audit, the time required to conduct this audit is not limited and could extend beyond what was initially scheduled to insure all required quality systems are thoroughly inspected and sufficient objective evidence gathered in the audit report. Scheme guidance should be follow when provided.

4. The AuditOne program relies on auditors with broad industry experience (15 years preferred), specialists in the areas being audited (3 years preferred), advanced degree(s), certifications, industry specific knowledge

5. AuditOne will request a CV for each auditor assigned to an AuditOne audit to ensure all established criteria have been met. Auditors must register on the AuditOne platform and provide a current CV for all auditors assigned to an AuditOne audit, please do so prior to the audit.

6. The AuditOne program requires the customer and auditor to have a pre-audit conference, providing an opportunity to review the customers experience with the supplier prior to the audit, both strengths and weaknesses, as well as discuss specific regulatory expectations for the standard being audited. This process relies on the supplier being audited providing their customers with the auditor's contact information prior to the audit. This communication will take place on the AuditOne Platform where the brand owner, auditor and supplier will interface. ***Please confirm, prior to executing the audit, that your auditor has had the opportunity to communicate with the participating brand owners.***

7. It is expected that the auditor is fluent in the language spoken at the site being audited. Where this isn't possible an independent translator is required.

8. Audit reports are to be written in English and uploaded to the AuditOne platform by the auditor or the certification body conducting the audit. AuditOne expects each element of the audit, audit summary, list of non-conformances and corrective action plans in English.

9. The scope of the audit must include all sites (manufacturing facilities, warehouses, off-site storage) coming in contact with the materials being manufactured under the scope of the audit. Distribution Centers are out of scope unless work is performed on the finished goods -ie trade customization

10. The auditor and certification body must be approved by the standard organization to conduct the audit, and must meet all of the ***standards organizations*** (scheme owner's) expectations and requirements as a pre-requisite to conducting the audit.

11. Please do not reference a Specific ***Brand or Consumer Products company's name*** in the audit report -this report will be shared among several customers/brand owners and confidentiality must be maintained

12. Harmonized definitions for Critical Findings

- Any nonconformance or non-compliance that will or already has adversely affected product or material performance from meeting approved specification, safety, therapeutic efficacy, or regulatory requirements.
- Any nonconformance or non-compliance which presents a risk to consumer /patient safety, performance of the material, or the customers reputation
- Any nonconformance or non-compliance that if allowed to continue, might result in product rejection, Field Action, or serious regulatory action (e.g., Warning Letter or similar).
- Repeat "Critical" or "Major" observation from a previous AuditOne audit or a failure to meet a commitment made to a regulatory authority.
- Observation represents the complete absence of one or more quality system elements or system components necessary to meet regulatory requirements as defined in the AuditOne applicable standard or addendum

Major Finding

- Where there is a substantial failure to meet the requirements of a 'statement of intent' or any clause of the module/standards
- Any non conformance or non-compliance versus the Quality and technical agreement between the organizations
- A situation is identified which would, on the basis of available objective evidence, raise significant doubt as to the conformity of the product or service to the AuditOne Standard. .
- An accumulation of minor observations which when considered in combination could present a systemic risk of a major outage

Minor Finding

- Where a clause of the AuditOne standard has not been fully met but, on the basis of objective evidence, the conformity of the product to the AuditOne Standard is not in doubt.
- Any one of non systemic outages which does not meet the above criteria

13. In the event of a ***critical finding*** -section 21 of the AuditOne Governance Document located at AuditOneGlobal.com must be followed within 24 hours of the finding.

14. When a supplier engages in an audit to the accepted AuditOne standard, with an AuditOne approved Certification Body, the completed audit once approved by the supplier, must be posted on the AuditOne portal by the CB.

The suppliers participating in the AuditOne program do not have the right to decide not to post a completed audit for any reason.
Participating CB's have been instructed to notify AuditOne (dave.hempson@auditoneglobal.com) in the event that a supplier fails to authorize the auditor to post a completed audit for any reason. In this case, all participating AuditOne customers will be notified and appropriate actions will be taken to protect consumers from undue risks.

15. Auditors are encouraged to recommend ***best practice*** suggestions to suppliers during the audit, or in the audit wrap up conference in areas that could be improved that do not rise to the level of a finding. These recommendations are not to be included in the audit report to avoid setting an expectation that these recommendations require action on behalf of the supplier.

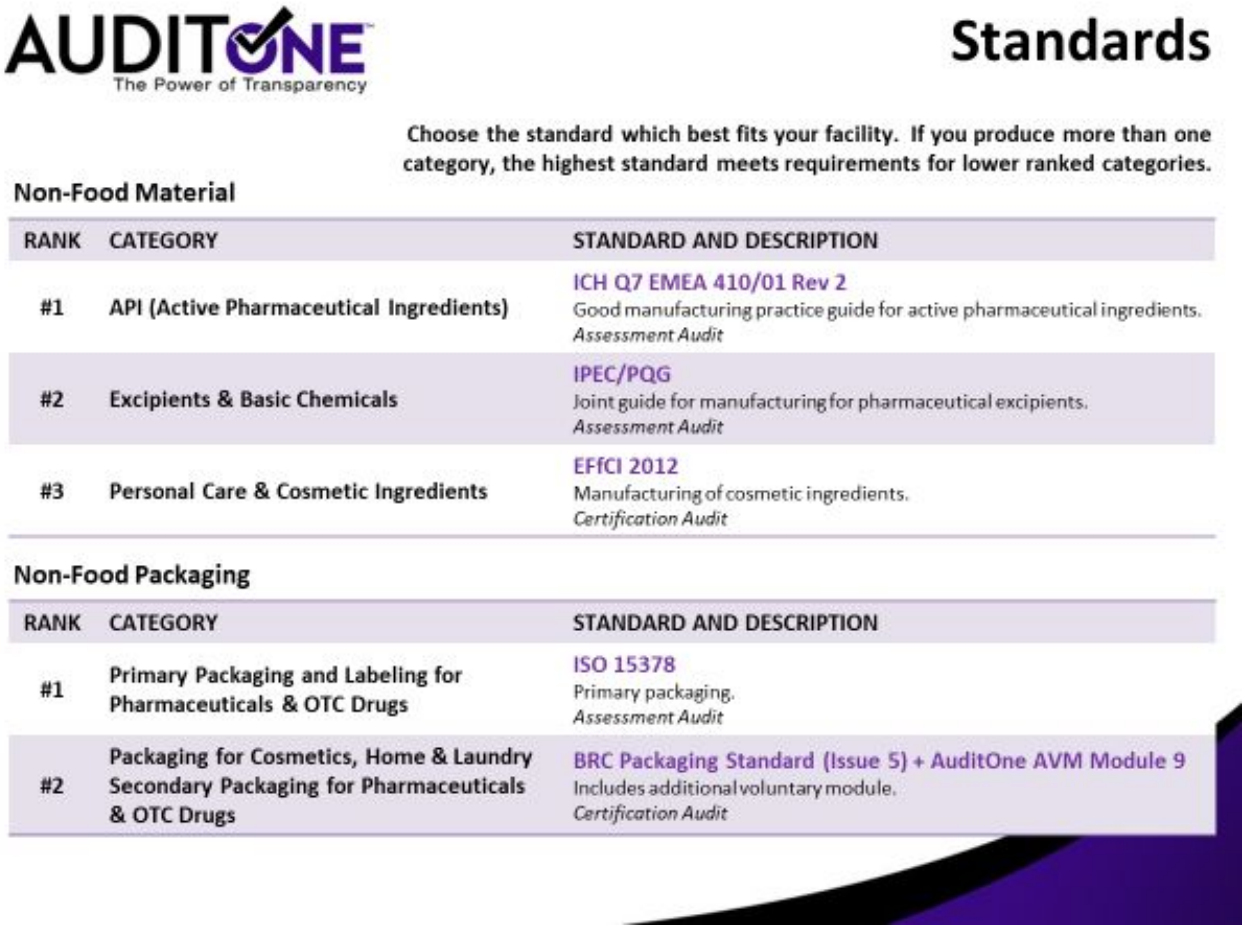
16. When an audit is scheduled with your firm please ensure that the supplier has conducted this activity on the AuditOne Platform.

17. AuditOne, the supplier, the customer and the audit firm (CB) will enter into a confidentiality agreement when registering for the AuditOne. The results of the audit will be maintained by the audit company and posted in PDF format to the secure AuditOne platform. The supplier will grant customers access to the AuditOne platform for the audit report and corresponding information. Confidentiality will be maintained by granting secure access to only authorized customers.

PROGRAM GOVERNANCE DOCUMENT

Please click the link here to access the Program Governance Document:
http://auditoneglobal.com/wp-content/uploads/2017/08/audit_one_program_governance_vol_3.pdf

STANDARDS CHART



AUDITONE
The Power of Transparency

Standards

Choose the standard which best fits your facility. If you produce more than one category, the highest standard meets requirements for lower ranked categories.

Non-Food Material

RANK	CATEGORY	STANDARD AND DESCRIPTION
#1	API (Active Pharmaceutical Ingredients)	ICH Q7 EMEA 410/01 Rev 2 Good manufacturing practice guide for active pharmaceutical ingredients. *Assessment Audit*
#2	Excipients & Basic Chemicals	IPEC/PQG Joint guide for manufacturing for pharmaceutical excipients. *Assessment Audit*
#3	Personal Care & Cosmetic Ingredients	EFfCI 2012 Manufacturing of cosmetic ingredients. *Certification Audit*

Non-Food Packaging

RANK	CATEGORY	STANDARD AND DESCRIPTION
#1	Primary Packaging and Labeling for Pharmaceuticals & OTC Drugs	ISO 15378 Primary packaging. *Assessment Audit*
#2	Packaging for Cosmetics, Home & Laundry Secondary Packaging for Pharmaceuticals & OTC Drugs	BRC Packaging Standard (Issue 5) + AuditOne AVM Module 9 Includes additional voluntary module. *Certification Audit*

2. ONBOARDING/QUALIFICATIONS

AUDIT STANDARDS & CB QUALIFICATIONS & APPROVAL PROCESS

AuditOne Audit Firm Approval Criteria – Revision 2 – July 2017

Audit Firm selection and approval criteria will include evaluation of the audit firm's individual processes by the *AuditOne CB team:*

The AuditOne initiative is open to all certification bodies that meet these established criteria and maintain standard body approval for the standards selected.

Auditor Approval Criteria

Describe the process utilized to qualify auditors. The AuditOne program relies on industry experience (15years preferred), specialists in the areas being audited (3 years preferred), engineering degree (s), advanced degrees (s), certifications, industry specific knowledge.

Auditors are required to provide evidence that they are accredited or certified to the standards they are auditing.

The CV for each auditor assigned to an AuditOne must be uploaded and available on the platform.

Auditor training program

Describe training to the standards required, what kind of training programs are employed, what is the frequency of training? Verify that your auditors meet the training expectations required by the standards organizations being utilized by the AuditOne program?

Auditor Evaluation Program Elements

How are field auditors evaluated by your firm -what system is utilized to ensure compliance with the audit standard being audited?

Frequency of company led witnessed audits to ensure compliance? How often are field auditors monitored and their effectiveness evaluated by the firm while in the field?

Firms auditor rating process

How does your firm maintain consistency across their audit staff, what calibration tools are utilized to ensure audit standards are consistently applied?

How does your firm meet the calibrations guidelines provided by the standards bodies?

Audit reports and auditor feedback

Will feedback from clients that have been audited be evaluated and trended on content, clarity, on-time-delivery, response time, formatting? If yes please describe your program.

Supplier feedback

Will feedback be collected following each audit engagement as part of the Audit Firm evaluation process?

Is feedback collected at the time of the final audit review with the supplier?

Note- Supplier Feedback will be reviewed by the F4SS QAHP Governance Committee following each audit.

Registration Requirements

For those standards requiring audit firm registration, approval, certification – please indicate your current registration status.

Certification Requirements.

Does your firm meet the certification standards utilized in the AuditOne program standards listed?

Communication Expectations

Does your firm provide an international network of local offices? -if so, please indicate locations

Who is the responsible person or team to provide communication with F4SS AuditOne team?

From time to time we will need your attendance at meeting, webinars, conference calls organized by F4SS AuditOne -any issues?

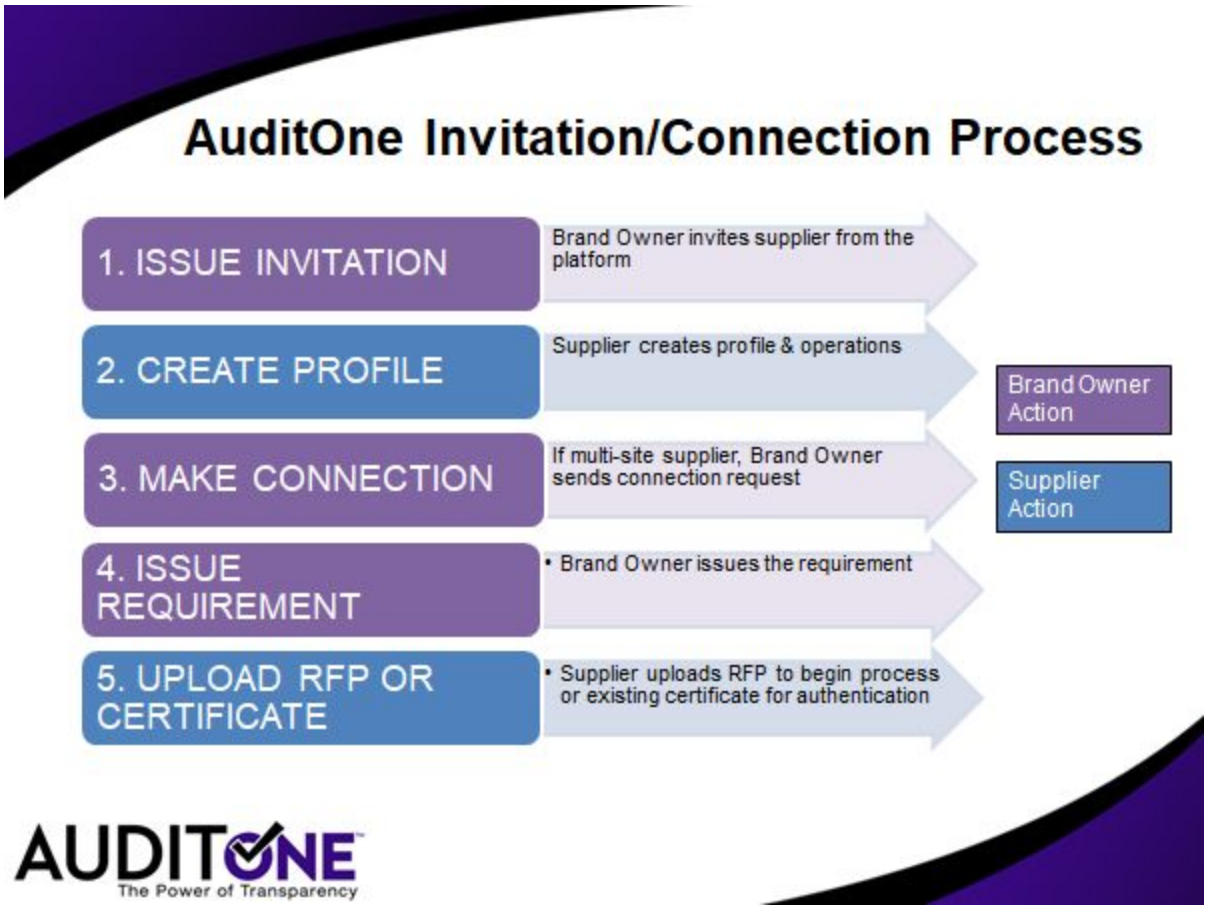
Consulting Relationships

We will need to verify that your auditor has not consulted with the firm being audited for a period of 2 years -please ensure that this expectation is met when assigning an auditor to a supplier of the AuditOne initiative

3. PLATFORM PROCESS OVERVIEW

INVITATIONS/CONNECTIONS

The process begins with brand owners inviting their suppliers to set up profiles on the AuditOne Platform, which is a platform ecosystem, much like Amazon, EBAY and Über. See below for an overview of the invitation & connection process flow.



REQUIREMENTS

Once brand owners are connected to their suppliers (or a supplier connects to their suppliers), documents and requirements can be shared. An audit request is an example of a requirement and can be issued by any customer in the process. Once received, the supplier can then request an audit quote from approved CBs certified to this standard.

The supplier will receive quotes from approved, participating CBs within 5 days, at which point a selection can be made, the audit scheduled, and paid. The audit date is recorded on the platform calendar and all impacted parties are advised.

Follow this link for an overview of the **Requirements Process**:
https://support.greenfence.com/hc/en-us/articles/115010344348-Requirement-Process-Overview

Follow this link for an a **CB guide to contracting the Audit:**
https://support.greenfence.com/hc/en-us/articles/115010357108-Stage-1-Contracting-for-the-audit-RFP-and-Contract-CB-

Audit Process

The CB conducts the audit and posts it securely on the audit platform. The CB continues the process with any CAPAs resulting from the audit. The quality audit itself is owned by the supplier and the supplier may securely share the results with any parties via the platform.

PRIVACY & CONFIDENTIALITY

Please follow this link for information on privacy & confientiality:
https://support.greenfence.com/hc/en-us/categories/203845788-Privacy

Please follow this link for the Privacy Policy:
http://auditoneglobal.com/wp-content/uploads/2017/05/AuditOne_Privacy_Policy.pdf

CB TERMS OF USE

Please follow this link and find section 24 of the terms of use for CBs:
http://www.greenfence.com/terms-of-use/

4. PAYMENT PROCESS/COST STRUCTURE

This provides an overview of the AuditOne process regarding quoting and payments.

PAYMENT TERMS

- Suppliers are expected to pay the all appropriate costs and fees no later than the time the audit plan is uploaded to the platform – target 4-6 week before the audit (option is available to pay when the contract is signed and uploaded but cannot view the audit plan until payment is made).
- The 25% platform referral fee is included in the amount collected at the time of the audit plan upload and should be included in the contract (see below for quote guidelines and referral fee structure).
- The money, once paid, is held in escrow until the certificate & audit report have been uploaded by the CB/Auditor - once complete, the money will be disbursed to the CB for audit costs and AuditOne for the platform referral fee. The CB will then be responsible for settling any relevant fees with scheme owners, accreditation bodies etc.
- Payment will be collected for year 1 or current year audit and fees only.

QUOTE GUIDELINES

The price quoted in the response to the RFP must include:

1. The AuditOne referral fee
    - Calculate this fee over the total of all other audit related costs and fees (Excludes expenses and platform referral fee).
2. All appropriate costs and fees up to the audit report upload.
    - Time for the audit onsite days and auditor travel time, to include Stage 1 and Stage 2 audits (if applicable)
    - Any gap assessments requested
    - Management fees
    - Scheme and accreditation fees
3. Payable terms – invoice is payable when the audit plan is uploaded
    - All supplier audit payments will be made to Greenfence on the AuditOne platform, before being issued to CBs.
        - Your audit proposals should make this clear to Suppliers as they will likely need to set up Greenfence as preferred vendor in their system.
        - The information and process to set up greenfence as a supplier is being built into the platform payment set up process. In the interim, this can be made available upon request.
4. All quotes and payments to be issued through US currency
5. Ensure the quote is signed when you submit to the supplier so they can simply sign, upload & accept on the platform

The price quoted should **not** include any expenses associated with the service or any costs associated with CAPA close out. You will be able to invoice these separately on the platform once they have been determined.

CANCELLATION POLICY

- If the Supplier cancels or reschedules 6 weeks or more prior to the scheduled audit dates a (25%) cancellation charge applies, unless waived by the Certifying Body.
- If the Company cancels or reschedules 3 to 6 weeks prior to the scheduled audit dates a (50%) cancellation charge applies, unless waived by the Certifying Body.
- If the Company cancels or reschedules 3 weeks or less prior to the scheduled audit dates a (100%) cancellation charge applies, unless waived by the Certifying Body.
- Supplier will be responsible for any non-refundable travel expenses the CB has incurred at the time of cancellation or reschedule.

CONTRACT INCLUSIONS/FORMAT

We recommend using the format below in contract quotes:

Audit Costs/day	1,000.00		
Audit Activity	**Audit Days**	**Cost**	
Gap Analysis	1.00	1,000.00	
Stage 1 Audit	2.00	2,000.00	
Stage 2 Audit	4.00	4,000.00	
Auditor Travel Time	2.00	2,000.00	
Scheme Fee		300.00	
Accreditiation Fee		200.00	
Sub-total		9,500.00	
Platform Fee		2,375.00	(25% of $9,500)
Total Quote		**11,875.00**	

Referral Fee Structure:

AuditOne Audit	Referral Fee	Value
Audit Services Conducted Through the Platform	25%[1]	Of gross invoice, excluding platform referral fee and expenses
Audit Conducted Outside Platform Process:		
· Uploaded by Aug 31, 2017	$500 +tax	Flat fee for all audits[2]
· Uploaded Sep 1 – Dec 31, 2017	$1,500 +tax	Flat fee for all audits[2]
· Uploaded from Jan 1, 2018	$2,000 +tax	For audits $5,000[2] or less
	$3,000 +tax	For audits $5,000 - $10,000[2]
	$6,000 + tax	For audits $10,000+[2]

[1] The 25% referral fee applies to all audit related services including pre-audits, initial and surveillance audits.

[2] Fees apply based on the gross total, excluding expenses and platform referral fees. The price quoted should not include any expenses associated with the service or any costs associated with CAPA close out. You will be able to charge these separately on the platform once they have been determined.

Calculating the Referral Fee:

The referral fee can be calculated by multiplying the total cost of the audit by .25.

Audit Fee Schedule Guide

Audit Billing	Referral Fee	Total Cost
$3,000	$750	**$3,750**
$5,000	$1,250	**$6,250**
$7,500	$1,875	**$9,375**
$10,000	$2,500	**$12,500**
$12,000	$3,000	**$15,000**

AUDIT DURATION CALCULATOR

Audit Guidance for schemes without man-day recommedations						
Add 1/2 day for AuditOne BRC Module 9	1-3 Processes			4-6 Processes		
	50 % of time on plant floor			50 % of time on plant floor		
	Facility Size - Sq. Ft. & Sq. M.			Facility Size - Sq. Ft. & Sq. M.		
Number of Employees	<100K sq.ft - <10K sq m.	100K -275K sq. ft. - 10K-25K sq. m.	>275 sq. ft. - > 25K sq. m.	<100K sq.ft. - <10K sq. m.	100K -275K sq. ft. - 10K-25K sq. m.	>275 sq. ft. - > 25K sq. m.
1 to 50	1.5 Days	1.5 Days	1.5 Days	2 Days	2 Days	2 Days
51 to 500	1.5 Days	2 Days	2.5 Days	2 Days	2.5 Days	3 Days
501 to 1500	2 Days	2 Days	2.5 Days	2.5 Days	2.5 Days	3 Days
>1500	2.5 Days	2.5 Days	3 Days	3 Days	3 Days	3.5 Days