



ASTRALEUS SERVICES PRIVATE LIMITED

Address: 405 4th floor, Sky Previlon, Nipanla Indore MP- 452010(India)

APPLICATION FORM

A. PRIMIRAY CLIENT INFORMATION:

Name of Company:								
Audit Location (Address)								
Scope of Certification								
Contact No.								
Email:								
Legal Registration								
Services required	QMS	<input type="checkbox"/>	EMS	<input type="checkbox"/>	OHS	<input type="checkbox"/>	FSMS	<input type="checkbox"/>
	13485	<input type="checkbox"/>	FSSSC	Others		Others	Others	<input type="checkbox"/>
	MD		22000	<input type="checkbox"/>		<input type="checkbox"/>		
	QMS							
Accreditation Required	NABCB		<input type="checkbox"/>	ASPL		<input type="checkbox"/>		
Mode of Audit	Physical / Onsite		<input type="checkbox"/>	Remote/Hybrid		<input type="checkbox"/>		
Type of Certification	Initial (Stage 1 and stage 2)	<input type="checkbox"/>	Transfer		<input type="checkbox"/>	Recertification		<input type="checkbox"/>
State of implementation of standards	Implemented		<input type="checkbox"/>	Not yet		<input type="checkbox"/>		

B. Staff and organization details

	Main office/Site	Additional Site (if any)	Temporary Site / Virtual site
Address			
Activities			
Critical Process			
Other Process			
Sub Scope			
Total No. of Employee: (For multi-site, indicate all sites to be covered under certification) (If there are any employees on site which you are claiming are out of Scope, please explain rationale for justification here)			
	Main Site	Additional Site	Temporary/Virtual site
Full time			
Part Time			
Shift(General A,B and C)			
Repetitive work			

C. Process & Legal requirement

Statutory & Regulatory Requirements: (Related to the Nature Work & Management System Certification)	
Outsourced Process: if any; which effects the conformity of the product/service	
In case of outsourced process, what type and extent of controls have been applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of your MS?	
In case of outsourced process what is the process of evaluation and determined organization's ability to meet your requirement and legal compliances?	

D. Special information:

1)QMS:ISO 9001

Quality Management System	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the category "design and development" included in the activities to be certified?		
Is there any process that affects product conformity outsourced?		
Exclusions if any? -Such as: Design..		

2). EMS:ISO 14001

Environmental Management System	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is there any process that affects product conformity outsourced?		



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Details of the sites; your company managing at the same time?	
A Register of Significant Environment aspect?	
An Environmental Management Manual?	
An Internal Environmental Audit Programme?	
Has the Internal Environmental Audit Programme been implemented?	
Have you identified list of significant aspects & license required?	
Storage condition & Permitted Quantities of hazardous material?	

3)OHSMS:ISO 45001

ISO 45001:2018	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Details of the sites; your company managing at the same time		
Key hazards and OH&S risks identified?		
Critical occupational health & safety risks identified?		
Main hazardous materials used in the processes?		
OHS Legal & Statutory Requirements?		

4)FSMS:ISO 22000

FSMS Certification ISO 22000:2018	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Details & Number of HACCP implementation or Study/CCP identified		
How much sites your company managing at the same time?		
No. of process lines?		
No of shifts?		
Define Seasonality Issue (Please specify the production period, if any)		
Define specific Issue for locality, industry, legislation, organization if any		
Does your company have Valid Certification for relevant Management System like QMS?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sterilization required or not and if how process implemented and controlled?		
Food chain category known? (A to K...)		

5)ISO 13485 MD QMS

What type of device as: Non-active Medical Device Active Medical Devices (Non-implantable) Active Implantable Medical Devices In Vitro Diagnostic Medical Devices (IVD) Devices Incorporating/Utilizing Specific Substances/Technologies Parts and Services	YES <input type="checkbox"/> NO <input type="checkbox"/>
Emergency Response and Contingency Plan?	YES <input type="checkbox"/> NO <input type="checkbox"/>
Statutory & Regulatory Requirements: (Related to the Medical Device manufacturing)-MDR?	
Is design Applicable?	
Technical area if known?	

6) FSSC 22000

Does your company have Valid Certification for relevant Food safety Management System like QMS/FSMS	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Do you recruit, train, and evaluate your teaching and administrative staff? AS per above standards specific requirements?		
Do you safeguard sensitive Food safety requirements as per customer specific requirements?		
Controls on the site/operating areas and machines for the Hygiene?		
Sanitisation controls with the alarm system for emergency?		
Laboratory facilities?		
Water,Air,Power supply and controls with quality?		



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Equipment suitability, cleaning and maintenance controls?	
Measures for prevention of cross contamination?	
Cleaning and sanitizing?	
Waste disposal plans and authorisation details with the license?	

7)Any Other Standard:

Number of employees involved in the (Management + Purchase + Compliance + Sales & Marketing)	
Has the organization documented the Management System?	
Has the organization implemented the Documented management System ?	

E. CERTIFICATION PROGRAMME REQUESTED

Initial Certification (Stage 1, Stage 2 audit)		Recertification	
Combination audit		Transfer Cum Surveillance	
In the case of several certification programmes, would you like the audits to be combined or carried out separately?			
If the answer is yes, please specify which combination			
IN case of recertification, please provide following information:			

F. Transfer of certificate Information:

Certificate number with CB details	Issue Date	Valid Until	Is there is any Change in Scope (give details)	Transition information if required	Important Change since initial audit and why transfer?

G. ADDITIONAL INFORMATION

Have You Specific Programme/Timescale For Achieving Registration?		
Have you called on the services of a consultant?		
If yes, please specify which one :		
Name of Business Developer:-		
Is any way Business developer/Promoting Firm involved other than marketing?		
Declaration: The information provide above is true to the best of our knowledge and Belief.		
Name		Seal & Signature
Designation		
Date		

H. For official use only.

FOR ASTRALEUS SERVICES PRIVATE LIMITED		
USE ONLY:-		
Does accreditation request is available with the ASPL (Refer accreditation letter)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does territory of the application is in active list (Refer accreditation letter)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does Scope demand is available with the ASPL (Refer accreditation letter)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does MSS request is available with ASPL (Refer Application/approval of AB//MSS documents)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
REVIEWED BY:		DATE:
Can the application be further processed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comment: (if Any)		

Guidance for filling out the form and reviewing the form for QMS, EMS, OH&SMS, FSMS, 13485 MD QMS



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AND FSSC 22000.

Effective Number of Personnel

The effective number of personnel consists of all personnel (permanent, temporary, and part-time) involved within the scope of certification including those working on each shift. When included within the scope of certification, it shall also include non-permanent (e.g. contractors) personnel. Dependent upon the hours worked, part-time personnel numbers and employees partially in scope may be reduced or increased and converted to an equivalent number of full-time personnel. (e.g. 30 part-time personnel working 4 hours/day equates to 15 full-time personnel.)

Additionally, OH&SMS shall also include personnel from contractors and subcontractors performing work or work-related activities that are under the control or influence of the organization, that can have an impact on the organization's OH&SMS performance. Reductions due to the employment of large numbers of unskilled personnel shall not be made without consideration of the associated OH&S risk.

Similar or repetitive process within scope - For QMS, EMS, OH&SMS, FSMS, 13485 MD QMS, FSSC 22000: -USE THE MANDAY TABLES OF ASPL and guidance from technical team on the scope, sites, Exclusions, Integration of MS(In case of IMS) Technical Areas, Food chain categories.

when a high percentage of personnel perform certain activities/positions that are considered repetitive (e.g. cleaners, security, transport, sales, call centers, etc.) a reduction to the number of personnel which is coherent and consistently applied on a company-to-company basis within the scope of certification is permitted. The methods incorporated for the reduction shall be documented to include any consideration of the risk of the activities/positions.

For OH&SMS:

- a) When a high percentage of personnel perform certain activities/positions that are considered similar or identical because they expose personnel to similar OH&S risks (e.g. cleaners, security, sales, call centres, etc.) a reduction in the number of personnel which is coherent and consistently applied on a company to company basis within the scope of certification is permitted. The methods incorporated for the reduction shall be documented to include any consideration of the risk of the activities/positions.
- b) For groups of workers performing repetitive jobs which can reduce attention, and raise the associated level of OH&S risk (e.g. mounting, assembling, packaging, sorting, etc.), the

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methods incorporated for possible reductions shall be documented to include the assessment of the OH&S risk of any activities/positions of workers.

For FSMS/FSSC 22000 -USE THE MANDAY TABLES OF ASPL and guidance from the supporting technical standards, technical team on the scope codes, exclusions, Technical Areas, Food chain categories.

The number of employees should be expressed as the number of full-time equivalent employees (FTEs). Certain categories are subject to multi-site sampling (see 9.1.5.2) and this may be taken into account when calculating the audit time. Other factors may necessitate increasing the minimum audit time (e.g. number of product types, number of product lines, product development, number of CCPs, number of operational PRPs, building area, infrastructure, in-house laboratory testing, need for a translator).

Note: Further Guidance

- 1. Please strike off whichever is not applicable. Please fill only relevant part of the form, Incomplete application form may not be considered and may be rejected.*
- 2. Temporary Site means a Location (physical or virtual) where a client organization performs specific work or provides a service for a finite period of time and which is not intended to become a permanent site.*
- 3. Virtual Site: An example of such a virtual site is a design & development organization with all employees performing work located remotely, working in a Cloud environment. A site cannot be considered a virtual site where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products.*
- 4. Application form can be filled online on MIS or may be submitted by filling in word or excel file.*
- 5. Acceptance of the application can be executed by QM/TM/TECHNICAL DIRECTOR, country head or any other authorized personal, acceptance of the application does not mean acceptance of application, but this is an acceptance of application for internal review purpose only.*