

BackOffice ServiceS – BOSS Program

*Easy
Medical
Device*

What is the BackOffice Services?

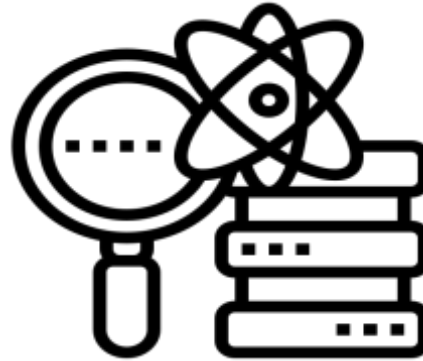
- Easy Medical Device is a consulting firm specializing in Quality and Regulatory Affairs for Medical Devices. We have worked with many customers and identified that they have some recurring needs.
- We then decided to create a Backoffice offer for them to manage their yearly budget. So no more surprises and the processes that you need us to take care of will be done on time.
- We know that within your company, you have some repetitive tasks that are done and you are willing to get some support to perform them, or you receive regular observations during audits because you miss some deadlines for your Management Review, supplier audits...



Overview Of The BackOffice ServiceS (Type of activities)



Internal Audit



**Postmarketing
Surveillance**



**Regulatory
intelligence**



Management Review



Trainings



Supplier audits

Overview Of The Internal Audit Services

Service name	Internal Audit
Service owner	EMD Team, The auditors will be qualified for multiple years of experience to the standards they are auditing.
Service topic	Internal audit services involve an independent and objective examination of an organization's quality processes, for that our team will keep track of your regular activities and then support your compliance process.
Service type	On-site or Virtually
Service place	On-Site in your company Virtually whether Teams or Google meet or Zoom
Service period	typically conducted annually or biennially.
Service Method	Before the delivery of the report, an internal process will verify its content and evaluate if this is compliant with the requirements of ISO 19011.
Service purpose or needs	Internal audit services purpose are to assess compliance, identify risks, and ensure effective internal controls, so, this service will help your company stay focused in the principal activity and in the same time you will gain performance and stability of your company

Overview Of The Postmarketing Surveillance Services

Service name	Postmarketing Surveillance
Service owner	EMD Team
Service topic	Postmarketing surveillance services are about monitoring a product's safety and effectiveness after it's available in the market, for that our team will keep track of your regular activities and then support your compliance process.
Service type	On-site or Virtually
Service place	On-Site in company Virtually whether Teams or Google meet or Zoom
Service date	After we agree on the PMS Plan at the start of the mission, we will then agree on a delivery time for the report.
Service period	Every year your company should perform a Postmarketing Surveillance. We can do that for you.
Service Method	We will use internal data that you will provide us and external data that we'll gather on the different databases to then provide you with the PMS report or PSUR.
Service purpose or needs	Postmarketing surveillance services purpose are to identify and address any issues that may arise during real-world use, for that this service will help your company stay focused in the principal activity and in the same time you will gain performance and stability of your company

Overview Of The Regulatory intelligence Services

Service name	Regulatory intelligence
Service owner	EMD Team
Service topic	Regulatory intelligence services involve staying updated on industry regulations, analyzing their impact, and providing information, for that our team will keep track of your regular activities and then support your compliance process.
Service type	Virtually
Service place	Virtually via Outlook
Service period	We will do that every month for you with a report that will be issued identifying all the standard updates and all the legislation changes that may impact your product or company.
Service Method	This report will include a summary of the changes so you can evaluate if this needs any actions from your side. This will be a personalized report specific to you.
Service purpose or needs	Regulatory intelligence services aim are helping businesses comply and making informed decisions in a changing regulatory landscape, thus this service will help your company stay focused in the principal activity and in the same time you will gain performance and stability of your company

Overview Of The Management Review Services

Service name	Management Review
Service owner	EMD Team
Service topic	Management review services entail the assessment and evaluation of an organization's managerial processes, practices and performance, for that our team will keep track of your regular activities and then support your compliance process.
Service type	Virtually
Service place	Virtually whether Teams or Google meet or Zoom
Service period	Per your agenda, we will prepare all the documentation needed for your Management Review.
Service Method	Planning, agenda, presentation, collection of actions, report, attendance list... We will execute your procedure and support your team to deliver all the necessary information.
Service purpose or needs	Management review services purpose are to ensure effective leadership, decision-making and overall efficiency, so, this service will help your company stay focused in the principal activity and in the same time you will gain performance and stability of your company

Overview Of The Training Services

Service name	Trainings
Service owner	EMD Team
Service topic	Training services involve the provision of instruction, education, or skill development to individuals or groups for that our team will keep track of your regular activities and then support your compliance process.
Service type	On-site or Virtually
Service place	On-Site in company Virtually whether Teams or Google meet or Zoom
Service period	Per our agenda and your needs, we will prepare all the documentations and supports needed.
Service Method	You can define regular training that should be done to your employees and we can deliver that per your requirements at a regular frequency
Service purpose or needs	Training services aim are enhancing the knowledge of individuals or their competencies in a specific subject, thus this service will help your company stay focused in the principal activity and in the same time you will gain performance and stability of your company

Overview Of The Supplier audits Services

Service name	Supplier audits
Service owner	EMD Team
Service topic	Supplier audits services involve checking and ensuring that a company's suppliers meet established standards and requirements, for that our team will keep track of your regular activities and then support your compliance process.
Service type	Virtually
Service place	Virtually whether Teams or Google meet or Zoom
Service period	typically conducted annually or biennially.
Service Method	As said these are just a sample of what we do actually for some companies. We have also done activities like recording of complaints for a company and management of the vigilance reporting.
Service purpose or needs	Supplier audits services purpose are to maintain a reliable and high-quality supply chain, for that this service will help your company stay focused in the principal activity and in the same time you will gain performance and stability of your company

How does The BackOffice ServiceS work?



Listening

We review with you your recurrent needs. And define a quote for the service which will be on a yearly basis.



Planning

We define the planning of delivery of each of the services.



Collecting

We collect the information that are needed to perform the activity.



Performing

We execute the task and inform you during the execution of the progress.



Delivering

We deliver the service on-time and review with you if this is satisfactory.

Backoffice service EMD contact

If you are curious about this offer, then contact us via our email: info@easymedicaldevice.com.

Send us the email with the informations below.

- Company name:
- Manufacturing activity:
- Which backoffice service is needed?:
- Location:

We will contact you after receiving it. And we will then take care of everything.

If you have any service you would like us to add, please don't hesitate to share it with us, we have a pleasure to hear from you,
Thanks in advance for your time