MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

GMP INSPECTIONS

Spanish Agency for Medicines and Medical Devices activities

Belén Escribano, PhD
Head of the Pharmaceutical Inspection and Enforcement Department of AEMPS

GMP Inspections – Legal basis

- Articles 40 and 46 Directive 2001/83 (HumanMP)
- Articles 44 and 80 Directive 2001/82 (VetMP)
- *Inspection procedures (Compilation EMA/572454/2014 Rev 17)*

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

- Article 64 of the consolidated text of the Law of guarantees and rational use of medicines and medical devices approved by the Royal Legislative Decree 1/2015, of July 24
- Articles 26, 43, 44 and 45 of Royal Decree 824/2010 of 25 June, regulating the manufacturing…

Key points:

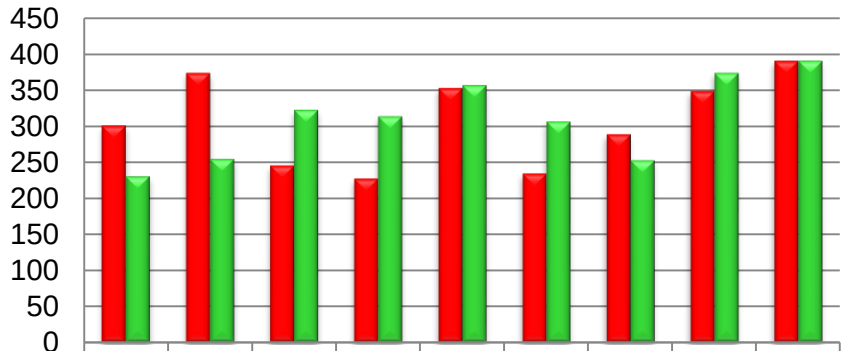
1.- Any manufacturing activity must be **authorised** and requires a **prior inspection**

2.- Medicinal products manufactured in Spain must **comply with EU GMP** guidelines even if they are manufactured for export only.

3.- **EU inspection procedures** must be followed

AEMPS GMP Inspection Activities

- Planning and performance of GMP inspections at **national and international** level (APIs & medicinal products)
  - Routine inspections: design and implementation of the Annual Inspection Programme:
    - National
    - International: sites in 3rd countries (EMA, AEMPS,WHO, EDQM)
  - Authorization inspections:
    - New sites
    - Major modifications of authorized sites
  - For cause inspections:
    - Non-compliance
    - Follow-up inspections
- Inspectors **training and qualification**



	2008	2009	2010	2011	2012	2013	2014	2015	2016
Inspection requests	301	374	246	228	353	235	289	349	391
Inspection activities	231	255	323	314	357	307	253	374	391

Annual Inspection Programme - Risk based model -

Objectives:

1. To achieve a **higher level of efficiency** in the use of inspection resources, prioritizing:
   - Inspections to be performed and areas or production lines to cover
   - Length and frequency
2. To protect effectively the **final quality**, controlling the most critical aspects

Methodology:

- Inspections are conducted **every 3 years** or less, depending on the result of the last inspection (validity period of the GMP certificate can be limited)
- A **priorization** is made taking into account risk factors, that can affect the product quality and are related to:
  - type of product,
  - manufacturing process,
  - facilities and
  - GMP history
- As a result, it is obtained an **ordered list of sites** to be inspected, according to a given punctuation, indicating: site name and address, dosage forms/APIs manufactured, last inspection date, number of days required, assigned team

Annual Inspection Programme - IT tool -

LABOFAR: the inspection programme is managed electronically. IT tool of the Pharmaceutical Inspection and Enforcement Department of AEMPS

- ✓ Two annual inspection programmes:

  Medicinal products
  - National
  - International

  Active pharmaceutical ingredients
  - National
  - International

- ✓ Documents generated:
  - ❑ Plan
  - ❑ Final Report: including results of inspection (compliance/date of inspection) and programme compliance

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Annual Inspection Programme - IT tool -

agencia española de medicamentos y productos sanitarios

labofar

PILAR FERNANDEZ DEL POZO BIEL
Zona: AEM
Versión: 1.2

Desconect

Pilar Fernandez del Pozo Bielza

Planificacion de la Actividades Inspectoras - PE009-361
Estado: Redacción del Informe Final de Actividades Inspectoras

Listado de instalaciones que potencialmente pueden ser incluidas en el PAI LABORATORIOS del año 2017

Ingresar búsqueda por nombre de instalación...
Ingresar búsqueda por expediente...

Buscar

Programa Nacional | Programa Internacional

103 filas, mostrando desde 1 a 20.
[<</<] 1, 2, 3, 4, 5, 6 [>/>>]

Expe.	Instalación	Dirección	F. Insp.	Mes	Prio. P.	Prio. F.	Insp. 1	Insp. 2	Criterios	¿Incl.?	Estado
PE010-1549	DIATER LABORATORIO DE DIAGNÓSTICO Y APLICACIONES TERAPÉUTICAS, S.A.	Avenida Gregorio Peces Barba, ...	05/09/2017	8	2.7	2.7	MMG	MRV	[A, D, E, F]	Sí	
PE010-1548	ZOETIS MANUFACTURING & RESEARCH SPAIN, S.L.	Ctra. de Camprodón, s/nº, Finc...	28/04/2017	4	2.7	2.7	LIPG	PAL	[A, D, E, F]	Sí	
PE010-1547	IBA MOLECULAR SPAIN, S.A.	Paseo Miramón, 182, San Sebast...	09/03/2017	2	2.7	2.7	MVA	JCJ	[D, F]	Sí	
PE010-1551	ROVI CONTRACT MANUFACTURING, S.L.	Julián Camarillo, 35, Madrid, ...	21/04/2017	5	2.3	2.3	LIPG	PFB	[A, D, E]	Sí	
PE010-1553	ROXALL Medicina España, S.A	Parque Científico y Tecnológic...	07/09/2017	8	2.3	2.3	MASA	ACS	[B, D, E]	Sí	
PE010-1552	PRAXIS PHARMACEUTICAL, S.A.	C/ Hermanos Lumiere 5, Parque ...	20/10/2014	9	2.3	2.3	MASA	JCJ	[A, D, E]	Sí	
PE010-1550	AMPLICEL SOLUCIONES DIAGNÓSTICAS, S.L.	Clínica Cemtro. Avda. Ventisqu...	20/04/2017	4	2.3	2.3	MMG	CFT	[A, D, E]	Sí	
PE010-1554	FARMASIERRA MANUFACTURING, S.L.	Ctra. Irún, Km. 26,200, San Se...	13/02/2017	2	2.2	2.2	SM	IRE	[A, D, E]	Sí	
PE010-1556	IBA MOLECULAR SPAIN, S.L.	C/ Marqués de Beccaría, 3, Cam...	10/02/2017	1	2.2	2.2	MVA	JCJ	[A, D, F]	Sí	
PE010-1555	IBA MOLECULAR SPAIN, S.A.	Thomas Alba Edison, 7, Sevilla...	16/03/2017	2	2.2	2.2	MVA	JCJ	[A, D, F]	Sí	

Redactar

¡Muchas gracias!