Organization Certifying Systems Japan Association for Pharmaceutical Affairs Law Foundation (JAPAL)

– To ensure appropriate management of Pharmaceutical law related tasks in your company –

1. Overview

Pharmaceutical law and related regulations needed to be properly operated in following organizations:

-Companies with manufacturer's license, marketing approval holder's license, sales license and repair license (*)

(*These licenses are based on Japanese Pharmaceutical law)

-Pharmacy, medical organization, testing organization, training organization

-Foreign companies, etc.

There are many possible problems during daily operations such as side effect of medicine, trouble of devices, customer complaints. But prompt action can be conducted if there are well-trained staff members with adequate knowledge and experiences.

JAPAL provides for third party audits to your company, to ensure appropriate management of Pharmaceutical law related operations.

2. Accreditation criterion (JAPAL.Cert.101101Ver.1) 2010/11/1

No.	Requirements	Compulsory	Reference
1	Well-trained staff member with adequate knowledge and experiences of Pharmaceutical law and related regulations.	○	
2	Appropriately conducting daily operations involving Pharmaceutical law and related regulations, e.g., producing label with legal description, advertising printing etc.	○	
3	Prompt action is conducted if problem arises, e.g., side effect of medicine, trouble of devices, customer complaints.	○	
4	Collection, review and implementation of measures are done with Pharmaceutical law related regulations and notices on regular basis.	○	
5	Practicing requirements of Pharmaceutical law, if company hold license.	○	
6	Staff members engage in Pharmaceutical law related operations take appropriate training on regular basis.	○	
7	No recall or noncompliance case (except for administrative guidance) related to Pharmaceutical law is occurred within last 3 years.	○	
8	Above 1 to 7 requirements are internally audited on regular basis, and are ready for review. System to be amended is built up based on review.	○	
9	Obtain ISO9001:2008 for the operations related to Pharmaceutical law.		○

10	[for Medical organization] Placing Safety management supervisor of medical devices, and establish operations.		○
11	[for Testing organization] Conducting tests and inspections concerning Pharmaceutical law and related regulations.		○
12	[for Training organization] Conducting training concerning Pharmaceutical law and related regulations.		○
13	[for Foreign companies] Built up scheme that smoothly collect information concerning Pharmaceutical law and related regulations.		○

3　Expire Date

1 year from accreditation date

4　Renewal of accreditation

Undergo audit by JAPAL certified auditor before expire date.

5　Fees

JPY 73,500 (1year)

※ JAPAL members admitted free.

※ Travel cost and accommodation fee are caused in case of on-site audit.

6　Steps

6-1) Submit application form and papers which are needed for document review

6-2) Document review

6-3) On-site review (if needed)

6-4) Corrective action (if needed)

6-5) Review by Accreditation committee

6-6) Get certified (if above committee certify)

7　Average processing period

30 business days

8　Auditor

JAPAL certified auditor: 1-2 personnel

9　Revision of criterion

Accreditation criterion take appropriate amendment if there is change in related laws and legal interpretation, or if JAPAL judge to require amendment.

10　Contact

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11　Certification format (see our HP… www.japal.org/contents/company_cert/002160.html)