PMDA-ATC Medical Devices Seminar 2017 (draft as of August 25, 2017)

Date: November 6-10, 2017　　Venue: PMDA Meeting rooms

<table>
<tr><th></th><th>DAY 1　Nov 6 (Mon)</th><th>DAY 2　Nov 7 (Tues)</th><th>DAY 3　Nov 8 (Wed)</th><th>DAY 4　Nov 9 (Thurs)</th><th>DAY 5　Nov 10 (Fri)</th></tr>
<tr><td rowspan="4">AM</td><td>9:00 - 10:00　Registration

10:00 - 10:15
Opening Ceremony, Photo Session</td><td rowspan="2">10:00 - 11:00
7.　GCP/GLP Inspection for Medical Devices</td><td rowspan="3">10:00 - 12:00
11.　Group Work on Review of Medical Devices
(Review cases where preparation of guidelines and/or training was required as a condition for approval)</td><td rowspan="8">16.　Site visit to a training facilitiy</td><td rowspan="3">10:00 - 12:00
17.　Group Work on Review of Medical Devices
(Review cases requiring discussion on clinical data etc)</td></tr>
<tr><td>10:15 - 10:30
1. Seminar Outline</td></tr>
<tr><td>10:30 - 11:00
2.　Outline of PMDA</td><td rowspan="2">11:00 - 12:00
8.　Quality Management System for Medical Devices</td></tr>
<tr><td>11:00 - 12:00
3.　Regulations, Ordinance and Current effort (Early conditional approval system, Remanufacturing system for single-use device, Sakigake-system, etc) for Medical Device in Japan</td><td></td></tr>
<tr><td colspan="4">Lunch</td><td></td></tr>
<tr><td rowspan="2">PM(1)</td><td rowspan="2">13:00 - 15:00
4.　Review and Approval of Medical Devices (definition, classification, development and review process, consultation, approval process, etc)</td><td rowspan="2">13:00 - 15:00
9.　Post-Marketing Safety Measures for Medical Devices, Medical Safety Measures, Package Inserts</td><td>13:00 - 14:00
12.　Patient registration system
(Post-market surveillance, IMDRF, etc)</td><td>13:00 - 14:00
18. Industry view for development of medical device</td></tr>
<tr><td>14:00 - 15:00
13.　Standards for Medical Devices
(utilization of international standards, etc)</td><td>14:00 -14:30
19.　Wrap-up

14:30 - 15:00
Closing Ceremony</td></tr>
<tr><td colspan="4">Break</td><td></td></tr>
<tr><td rowspan="2">PM(2)</td><td>15:30 - 16:30
5.　Review of personalized medicine, 3D printer, etc</td><td rowspan="2">15:30 - 17:30
10.　Introduction of　Regulations by participants</td><td>15:30 - 16:30
14.　Review of IVD</td><td rowspan="2"></td></tr>
<tr><td>16:30 - 17:30
6.　Review of software, Judgement of product as medical device or not ,etc</td><td>16:30 - 17:30
15.　Collaboration　with FDA
(Harmonization By Doing)</td></tr>
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