****Resume

**[FIRST NAME] [LAST NAME]**

**PERSONAL DATA**

|  |  |  |  |
| --- | --- | --- | --- |
| Address: | Add or edit text | E‑mail: | example@mail.com |
| Phone: | 0 00000 00000 | Mobile: | 0 00000 00000 |
| Date of birth: | YYYY/MM/DD | Birthplace: | Add text |

**SUMMARY**

* Six years of experience in regulatory PMDA approval of Class I to IV, New, Improved and me-too medical device
* Strong knowledge of development of a QMS and an external audit, liaising with QA managers of manufacturer sites abroad.

**EXPERIENCE**

|  |
| --- |
| **Job title** in **Department** XY, **company, Location (MM/YYYYY -** Present**)** |
| **Responsibility** * Plan and coordinate regulatory strategies for new and modified radiological devices.
* Submission and obtaining approval of XXXX
* Reimbursement applied on XXXX
* Involved worldwide RA data streamline project
* Complaint handling of medical device

**Achievement*** The first approval of XXXX in Japan
* Obtained a Class III new medical device approval for: XXX
* Obtained a Class IV new medical device approval for: XXX
* XXX Award
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| **Job title** in **Department** XY, **Company, Location (MM/YYYY - MM/YYYYY)** |
| **Responsibility** * Experienced all process of PMDA Approval for Class I to IV device of Cardiac Surgery and Structural Intervention such as: XXX, XXXX, XXXX and other products.
* Experienced all category of medical device submission - New, Improved and Me-too. (Documentation, Submission, Presentation, Negotiation with PMDA for the test only for Japan, Answer to Inquiries, Get approval and Register reimbursement.)

**Achievement*** Obtained a Class III new medical device approval for XXXX as the very first approval under new Pharmaceutical Affairs Law in this company.
* Got C1 New category reimbursement by Documentation, Presentation in front of external experts.
* Created a draft of IB for Japan Clinical study
 |

Resume****

**[FIRST NAME] [LAST NAME]**

**LANGUAGES AND QUALIFICATIONS**

Language 1

Language 2

Language 3

**TECHNICAL KNOWLEDGE**

XY 1, XY 2, XY 3, etc.

XY 1, XY 2, XY 3, etc.

XY 1, XY 2, XY 3, etc.

**EDUCATION**

|  |
| --- |
| **Course of study, Grade: X,X (YYYYYY)** |
| University, Location  |
| * Focus points: XY 1, XY 2, XY 3, etc.
 |
| **Education (JJJJ - YYYY)** |
| Company, Location |
| * Focus points: XY 1, XY 2, XY 3, etc.
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