Introduction to Regulatory Affairs

By Hye-Ryon Kim, DVM, MS
Agenda

• Regulatory affairs(RA)의 정의 및 범위

• 법적 규제의 필요성

• IND, NDA의 이해

• 임상시험 관련 국내 법규의 이해

• 실무적 차원에서 RA 담당자의 역할

• Case study
Definition of Regulatory Affairs

• Definitions of Regulatory affairs (RA)
  
  – A discipline that focuses on the analysis and application of regulations in relation to the development, government approval and marketing of healthcare products.

  – Science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.

  – A comparatively new profession which developed from the desire of governments to protect public health by controlling the safety and efficacy of products

  – A new class of professionals emerged to handle regulatory matters for companies
Agenda

• Regulatory affairs (RA)의 정의 및 범위

  • 법적 규제의 필요성

• IND, NDA의 이해

• 임상시험 관련 국내 관련 법규의 이해

• 실무적 차원에서 RA 담당자의 역할

• Case study
Before FD&C ACT

- **Virus Toxin Law (Biologics Control Act) of 1902**
  - Diphtheria antitoxin from milk wagon horse tragedy in 1901 => 13 children died
  - First control over the manufacturing processes of biological products
  - Mandated that producers of vaccines be licensed annually
  - Inspections for the manufacturing facilities
  - All product labels were required to include the product name, expiration date, and address and license number of the manufacture

http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/100YearsofBiologicsRegulation/ucm070022.htm
Before FD&C ACT

- Pure Food and Drug Act of 1906
  - Prohibited interstate commerce of misbranded and adulterated foods and drugs
  - Allowed for seizure and criminal penalties
  - Enforced by Bureau of Chemistry
  - Regulation of product labeling rather than pre-market approval
  - Focused on foods

http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm
Before FD&C ACT

- **Elixir of Sulfanilamide Disaster of 1937**
  - Liquid form of sulfanilamide produced using diethylene glycol as solvent
  - Diethylene glycol = antifreeze
  - Administered to mostly children to treat streptococcal infections
  - Existing laws did not require any kind of pharmacological studies demonstrating that a drug is safe
  - 107 people died

[FDA Webpage](http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm)
1938 Food, Drug and Cosmetic Act (FD&C ACT)
- Extended control to cosmetics and therapeutic devices
- Required that drugs be labeled with adequate directions for safe use
- Required new drugs to be demonstrated as safe before marketing
- Provided standards
- Authorized factory inspections
After FD&C ACT

- Thalidomide babies – 1961
  - Hailed as wonder drug for sleeplessness
  - Relieved many morning sickness symptoms in pregnant woman
  - Unknown that Thalidomide crossed the placental wall
  - Catastrophic results
    - Peripheral neuritis – nerve disorder
    - Birth defects – deafness, blindness, disfigurement, cleft palette, internal defects, phocomelia
After FD&C ACT

- **Kefauver-Harris Drug Amendments in 1962**
  - First time manufacturers were required to prove effectiveness and safety of drug before marketing
  - Required to give participants full information about the benefits and risks of drugs being studied
  - Set good manufacturing practices to be followed by the drug industry
  - Also required that drugs introduced between 1938 and 1962 be effective - nearly 40% not effective

http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117831.htm
In Late 20th Century to 21st Century

- Food and Drug Modernization Act (FDAMA) in 1997
  - Reauthorization of Prescription Drug User Fee Act (PDUFA)
  - FDA Initiatives and Programs
  - Information on Off-label Use and Drug Economics
  - Pharmacy Compounding
  - Risk-based Regulation of Medical Devices
  - Standards for Medical Products
In Late 20th Century to 21st Century

- FDA Safety and Innovation Act (FDASIA) signed in 2012
  - Reauthorization of Prescription Drug User Fee Act (PDUFA)
  - Reauthorization of Medical Device User Fee Agreement (MDUFA)
  - Established generic drug and biosimilar biological product user fees
  - Addressed pediatric drug research, medical device regulation, pharmaceutical supply chain security, antibiotic development incentives, expedited drug approval, drug shortages,
In Late 20th Century to 21st Century

- Median Approval Times, New Molecular Entities (NMEs) & New Biologic Entities (NBEs), by Fiscal Year of Receipt
In Late 20th Century to 21st Century

- Review Performance for FY 2012

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Number Filed**</th>
<th>2012 Performance Goal</th>
<th>Potential Performance % of Actions Within Goal***</th>
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<tr>
<td>New Drug Applications / Biologic License Applications***</td>
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<td>Standard</td>
<td>96</td>
<td>90% in 10 months</td>
<td>100%</td>
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<tr>
<td>Priority</td>
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<td>96%</td>
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<td>NMEs/New BLAs</td>
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<tr>
<td>Standard</td>
<td>27</td>
<td>90% in 10 months</td>
<td>100%</td>
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<tr>
<td>Priority</td>
<td>16</td>
<td>90% in 6 months</td>
<td>94%</td>
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<td>NDA / BLA Resubmissions</td>
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<tr>
<td>Class 1</td>
<td>7</td>
<td>90% in 2 months</td>
<td>100%</td>
</tr>
<tr>
<td>Class 2</td>
<td>32</td>
<td>90% in 6 months</td>
<td>100%</td>
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<tr>
<td>NDA / BLA Efficacy Supplements</td>
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<tr>
<td>Standard</td>
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<td>Priority</td>
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<tr>
<td>NDA / BLA Efficacy Supplement Resubmissions</td>
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<tr>
<td>Class 1</td>
<td>2</td>
<td>90% in 2 months</td>
<td>100%</td>
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<tr>
<td>Class 2</td>
<td>14</td>
<td>90% in 6 months</td>
<td>86%</td>
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<tr>
<td>NDA / BLA Manufacturing Supplements</td>
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<td>Requiring Prior Approval</td>
<td>716</td>
<td>90% in 4 months</td>
<td>94%</td>
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<tr>
<td>CBE</td>
<td>1055</td>
<td>90% in 6 months</td>
<td>98%</td>
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- Data as of September 30, 2012.
In Late 20th Century to 21st Century

- **PDUFA V fee schedule for FY2014**
  - Applications
    - requiring clinical data: $2,169,100
    - not requiring clinical data: $1,084,550
    - Supplements requiring clinical data: $1,084,550
  - Establishments: $554,600
  - Products: $104,060

- **MDUFA III fee schedule for FY2014**
  - Premarket application (PMA, BLA, PDP): $258,520
  - Panel-track PMA supplement: $193,890
  - BLA efficacy supplement: $258,520
  - 180-Day PMA supplement: $38,778
  - Real-time PMA supplement: $18,096
  - Premarket notification (510(k)): $5,170
  - Establishment registration fee: $3,313
Law and Regulations

• Relevant Laws
  – Federal Food, Drugs, and Cosmetic Act
  – Public Health Services Act—Part F
    Licensing of Biological Products and Clinical Laboratories

• Relevant Regulations
  – Code of Federal Regulations (CFR) – see next page

• Other Guidelines
  – GxP: GCP, GMP, GLP, GCLP, GVP, GCDMP
  – Common Rule by HHS (Dpt. Of Health and Human Services)
  – Helsinki declaration by WMA(1964) <- Nuremberg Code(1947)

ICH: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
GCP: Good Clinical Practice, GMP: Good Manufacturing Practice, GLP: Good Laboratory Practice,
GCLP: Good Clinical Laboratory Practice, GVP: Good Pharmacovigilance Practice,
GCDMP: Good Clinical Data Management Practice
WMA: World Medical Association, WHO: World Health Organization
Code of Federal Regulations

- **U.S. Codes of Federal Regulations (CFR) for Clinical Trials**

<table>
<thead>
<tr>
<th>CFR Number</th>
<th>Regulations</th>
</tr>
</thead>
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<tr>
<td>21 CFR 11</td>
<td>Electronic records, electronic signatures</td>
</tr>
<tr>
<td>21 CFR 50</td>
<td>Protection of human subjects</td>
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<tr>
<td>21 CFR 54</td>
<td>Financial Disclosure by Clinical Investigators</td>
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<tr>
<td>21 CFR 56</td>
<td>Institutional review boards (IRB)</td>
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<tr>
<td>21 CFR 312</td>
<td>Investigational new drug application (IND)</td>
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<tr>
<td>Subpart I</td>
<td>Expanded Access to Investigational Drugs for Treatment Use</td>
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<tr>
<td>21 CFR 314</td>
<td>New drug application (NDA)</td>
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<td>Subpart C</td>
<td>Abbreviated application</td>
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<td>Subpart H</td>
<td>Accelerated approval</td>
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<tr>
<td>21 CFR 601</td>
<td>Applications for FDA approval of a biological license</td>
</tr>
<tr>
<td>Subpart E</td>
<td>Accelerated approval</td>
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# Code of Federal Regulations

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<tr>
<td>21 CFR 316</td>
<td>Orphan drugs</td>
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<tr>
<td>21 CFR 320</td>
<td>Bioavailability and bioequivalence requirements</td>
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<tr>
<td>21 CFR 330</td>
<td>Over-the-counter (OTC) human drugs</td>
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<tr>
<td>21 CFR 812</td>
<td>Investigational device exemptions (IDE)</td>
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<td>21 CFR 814</td>
<td>Premarket approval of medical devices (PMA)</td>
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<td>21 CFR 60</td>
<td>Patent term restoration</td>
</tr>
<tr>
<td>21 CFR 201</td>
<td>Labeling</td>
</tr>
<tr>
<td>21 CFR 202</td>
<td>Prescription drug advertising</td>
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</table>
U.S. Food and Drug Administration

- FDA organization chart

- CDER: IND & NDA for new drugs, orphan drugs, & OTC human drugs, ANDA for generic drugs
- CBER: BLA for biologics
- CDRH: IDE & PMA for medical devices

- Combination Products
  - 1991 - Intercenter agreement for assignment of a combined product and intercenter consultation
  - 2002 – Office of Combination Products
  - 2005 - Final Rule for Primary Mode of Action
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- Case study
In Terms of Process

- New drug development is a long journey.

IND: Investigational New Drug Application
NDA: New Drug Application
Pre-IND Meeting

• 근거: 21 CFR 312.82
• 목적
  – 임상시험 실시에 필요한 동물 시험 디자인의 검토 및 합의
  – 1상 임상시험 디자인 협의
  – 기타 협의(예: 소아 임상 실시 계획, IND data 제출 형식)
• Type B meeting: FDA가 서면 요청을 받은 날로부터 60일 이내에 실시
  – Pre-IND(PIND) file이 접수되면 PIND 번호 부여됨.
• 서면 요청서에 포함될 내용(모든 FDA와의 meeting에 공통 적용 사항)
  – 제품명, 일반명, 구조, 신청 번호(있을 경우), 예상 적응증, 용량 및 용법
  – 회의 종류(type A, B, C), 회의 목적 및 논의 목록(목록별 소요 시간 포함)
  – CMC, 약리/독성, 임상 항목 별로 질문 사항
  – 의료자측 참석자 목록, 참석하기를 바라는 FDA 관계자
  – 회의 날짜(6-8주 후로 신청)
  – 배경 자료 (회의일로부터 4주 이전에 제출)
Pre-IND Meeting

• Pre-IND meeting이 필요한 경우
  – Novel indication
  – No current Guidance Documents
  – Unique molecular entity, studies or indications
  – New sponsors or new to area of drug development
  – Problematic Pharm/Tox signals
  – New molecular entity
  – Avoid protocol changes

• 흔히 발견된 문제점
  – 불충분한 CMC, 전임상 자료
  – 부적절한 임상 디자인, GCP에 어긋나는 디자인
  – 용량 선정 근거 부족
Investigational New Drug Application

• IND 검토 목적
  – 피험자의 안전과 권리 확보 여부 확인
  – 임상시험(2상, 3상)이 약의 유효성과 안전성 평가에 적합하도록 과학적으로 설계되었는지 확인

• IND Dossier
  – Cover sheet
  – Table of contents
  – Investigational plan
  – Investigator’s brochure
  – Protocol
  – Chemistry, manufacturing, and controls information
  – Pharmacology and toxicology information
  – Previous human experiences with the investigational drug
  – Additional information
  – Relevant information
End of Phase 1 Meeting

- 근거: 21 CFR 312.82

- 주로 accelerate approval을 득하고자 하는 경우 실시

- Type B meeting: FDA가 서면 요청을 받은 날로부터 60일 이내에 실시

- 목적
  - 2상 임상시험 디자인의 검토 및 합의
  - 소아 임상시험 필요성 및 디자인, 시기 등 논의
End of Phase 2 Meeting

- 근거: 21 CFR 312.47

- Type B meeting: FDA가 서면 요청을 받은 날로부터 60일 이내에 실시

- 목적
  - 3상 임상시험 디자인, 대상 환자군, 샘플 사이즈, 평가 변수의 검토 및 합의
  - PK 시험 결과 업데이트 및 추가 임상시험 필요성 논의
  - 임상에서 적용할 용량, 치료 기간, 투여 경로, 제형 측면에서 전임상 결과가 충분히 뒷받침하고 있는지 확인
  - 시판 제형 및 기타 CMC 이슈 논의

- 준비 자료
  - 1상 및 2상 시험 결과 요약
  - 3상 임상시험 계획에 대한 개요와 계획서
  - 소아 임상 및 추가적인 전임상 시험 계획
Pediatric Study Plan

• Regulatory Actions for Protection of Safety of Pediatric Population
  – 1979 – Pediatric Use Subsection of Labeling (21 CFR 201.57 (f)(9))
  – 1994 – Pediatric Rule revised 21 CFR 201.57(f)(9) with added subsection (iv) on using extrapolation as a basis for Pediatric Use
  – 1997 – FDAMA: initial pediatric incentive program
  – 1998 - Pediatric Rule- mandated pediatric studies under particular circumstances
  – 2001 - Subpart D: Additional Safeguards for Children in Clinical Investigations of FDA-regulated products
  – 2002 - Best Pharmaceuticals for Children Act (BPCA)
  – 2003 - Pediatric Research Equity Act (PREA)
  – 2007 - Both reauthorized under FDAAA
  – 2012 - Both made permanent under FDASIA

• Pediatric Study Plan (PSP)
  – Study objectives and design, Age groups to be studied
  – Relevant endpoints, Statistical approach
  – Request for deferral, partial waiver, or full waiver
Pre-NDA Meeting

• 근거: 21 CFR 312.47

• Type B meeting: FDA가 서면 요청을 받은 날로부터 60일 이내에 실시
• NDA submission 예정일로부터 2개월 이전에 미팅이 이루어지는 것이 바람직함

• 목적
  – NDA dossier의 적절성(내용, 형식) 확인
  – FDA 검토자와 배경 정보를 미리 공유
  – 통계학적 분석법 등 논의
  – 소아에서의 안전성과 유효성을 뒷받침할 임상 자료가 있는지/필요성 등 확인
  – Delayed submission (original NDA 제출 후 30일 이내 제출) 자료 합의: stability data, final audited reports(일부 전임상 시험에 해당)

• 준비 자료
  – 실시한 임상 시험의 간략한 요약
  – 소아 임상시험 필요성 및 실시 정보
  – 신청 서류 양식 및 데이터 제시 방법
New Drug Application

• NDA 검토 관점
  – 시험약을 지시된 대로 사용하였을 때 신청한 적응증에 대해 약의 안전성과 유효성이 입증되었는가? 약의 사용으로 인한 이점이 위험성을 상회하는가?
  – 신청한 labeling 내용이 적절하고 필요한 정보를 모두 담고 있는가?
  – 시험약의 제조 방법이 약의 특성, 함량/역가, 품질, 순도를 유지하는 데에 적절한가?

• NDA Dossier
  – Module 1 Administrative Information and Prescribing Information
  – Module 2 CTD summary
  – Module 3 Quality
  – Module 4 Non-clinical study reports
  – Module 5 Clinical study reports
**New Drug Application Timeline**

- **Advisory committee meeting**
  - New molecular entities or novel biologics
  - Unconventional clinical or surrogate endpoints used in pivotal study
  - Significant issues related with safety or efficacy

- **Resubmission timeline**
  - Class 1 resubmission: 2개월
  - Class 2 resubmission: 6개월

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**Filing Period**

- Day 0: Filing meeting
- Day 45: Filing letter
- Day 60: Internal mid-cycle review meeting

**Review Period (standard 10 mo.; priority 6 mo.)**

- Day 74 letter

**Launch**

- NDA approval

**Timeline Diagram**

- Day 0
- Day 45
- Day 60
- NDA approval

**Additional Details**

- **Filing Period**
- **Review Period**
- **Launch**
Expediting Availability of New Drugs for Serious Conditions

- **Fast Track**
  - Drugs for serious conditions (AIDS, Alzheimer’s, heart failure, cancer)
  - Drugs filling an unmet medical need
  - 기존 치료제가 있을 경우
    - Showing superior effectiveness
    - Avoiding serious side effects of an available therapy
    - Improving the diagnosis of a serious condition where early diagnosis results in an improved outcome
    - Decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment
    - Ability to address emerging or anticipated public health need

- **Fast Track designation 요청** => 60일 이내에 FDA 회신

- Eligibility for Accelerated Approval and Priority Review
- Rolling Review
Expediting Availability of New Drugs for Serious Conditions

- **Breakthrough Therapy**
  - Drugs to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).
  - Intermediate clinical endpoint
    - Measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug (effect on irreversible morbidity and mortality)

- **A drug that receives Breakthrough Therapy designation is eligible for the following:**
  - All Fast Track designation features
  - Intensive guidance on an efficient drug development program, beginning as early as Phase 1
  - Organizational commitment involving senior managers

- **Breakthrough Therapy designation 신청 => 60일 이내에 FDA 회신**
  - 늦어도 EOP2 meeting 까지 신청
Expediting Availability of New Drugs for Serious Conditions

- **Accelerated Approval**
  - 1992 – Subpart H added
  - Allowing drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint or intermediate clinical endpoint
  - 허가 후 phase 4 confirmatory trials

- **Priority Review**
  - Under PDUFA in 1992
  - 기존 치료법에 비해 상당한 개선점이 있는 약에 적용
    - evidence of increased effectiveness in treatment, prevention, or diagnosis of condition
    - elimination or substantial reduction of a treatment-limiting drug reaction
    - documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes
    - evidence of safety and effectiveness in a new subpopulation
  - FDA가 결정. 의뢰자가 신청 가능.
  - 임상시험 기간을 단축하거나 검토 시 고려하게 되는 evidence의 양과 질에 영향이 없음
  - Original NDA/BLA 접수 후 60일 이내에 회신
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Related Domestic Laws and Regulations

- 약사법
  - 제34조(임상시험 계획의 승인 등)
  - 식품의약품안전처장의 승인
  - Vulnerable subjects를 시험대상으로 해서는 안 됨
  - 임상시험용의약품은 GMP 시설에서 제조되어야 함
  - 안전성 등에 중요한 문제가 발생하는 경우 필요한 조치를 취하도록

- 약사법시행규칙
  - 제31조(임상시험계획의 승인 등)
  - 제32조(임상시험의 실시기준)
  - 제33조(임상시험책임자 등의 교육)
  - 제34조(임상시험용 의약품등의 사용금지 등)

- 의약품임상시험계획승인지침(IND)
- 의약품임상시험관리기준(KGCP)
- 의약품임상시험 실시기관 지정에 관한 규정
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시행령
약사법 시행령 [시행 2014.1.1] [대통령령 제25050호, 2013.12.30, 타법개정]

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[시행 2013.3.23] [총리령 제1022호, 2013.3.23, 제정]

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[시행 2013.12.31] [농림축산식품부령 제69호, 2013.12.31, 일부개정]

[시행 2013.3.23] [총리령 제1022호, 2013.3.23, 타법개정]

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Agenda

• Regulatory affairs(RA)의 정의 및 범위
• 법적 규제의 필요성
• IND, NDA의 이해
• 임상시험 관련 국내 법규의 이해

• 실무적 차원에서 RA 담당자의 역할
• Case study
Qualification of RA Professionals

- RA 전문가가 되려면...
  - 과학적 관심, 훈련, 경험
  - 법 및 규정에 대한 관심
  - Good writing skills!
  - 협상 기술
  - 경청의 자세
  - 내외부 관련자와의 소통 기술
  - 세부 사항을 파악하는 능력
  - 분석적인 마인드
  - 자료의 정리 및 구분 능력
  - 프로젝트 관리 능력
Qualification of RA Professionals

Prior Professional Experience

- 28% Research & Development
- 21% Quality
- 8% Lab Sciences
- 7% Engineering
- 6% Clinical Research
- 5% Pharmacy/Pharmacology

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Career Path of RA Professionals

[Diagram showing job titles and their percentages: Coordinator 2%, Consultant 7%, Associate 9%, Specialist 20%, Project Manager 5%, Manager 25%, Vice President 7%, Director 22%, CEO/President 3%]

RAPS 2012 scope of practice & compensation report
Career Path of RA Professionals

[Diagram showing years of professional experience for different roles such as Vice President, Director, Manager, Project Manager, Specialist, and Associate.

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Career Path of RA Professionals

![Pie chart showing employment settings: Industry 72.9%, Consulting 13.7%, Govt/Notified Body 3.5%, Hospital/Medical Practice 1%, CRO 3.8%, Academic 2%, Research Organization 3%.]

RAPS 2012 scope of practice & compensation report
Roles of RA Professionals in Relation with Product Lifecycle
References and Resources

- US FDA NDA process
- Regulatory Affairs Professional Society (RAPS)
- Canadian Association of Professionals in Regulatory Affairs
- The Organisation for Professionals in Regulatory Affairs