生涯講座系列 33-

求職路上的疑難雜症

台灣大昌華嘉股份有限公司
醫療保健事業部 法規專員

林珮雯(101級)
Pewen.lin@gmail.com

Delivering growth – in Asia and beyond.

工作經歷

學術界　　產業界

IMM畢業(2016) → 輔仁大學醫學院 → 保吉生化學股份有限公司 → 德瑪凱股份有限公司 → 台灣大昌華嘉股份有限公司

2016.10 - 2017.07
研究助理

2017.10 - 2019.04
產品查登專員

中型本土企業
- 臨床檢驗試劑
- 實驗室耗材
- 檢驗中心
- 健檢中心

2019.05 - 2020.10
法規專員

小型新創公司
- 醫美醫材代理
- 微創醫材代理
- AED製造商

2020.11 - Present
藥事法規專員

外商公司
- 市場拓展(B2B,B2C)
- 物流業
- Sanofi, BMS, Pfizer, Alcon…

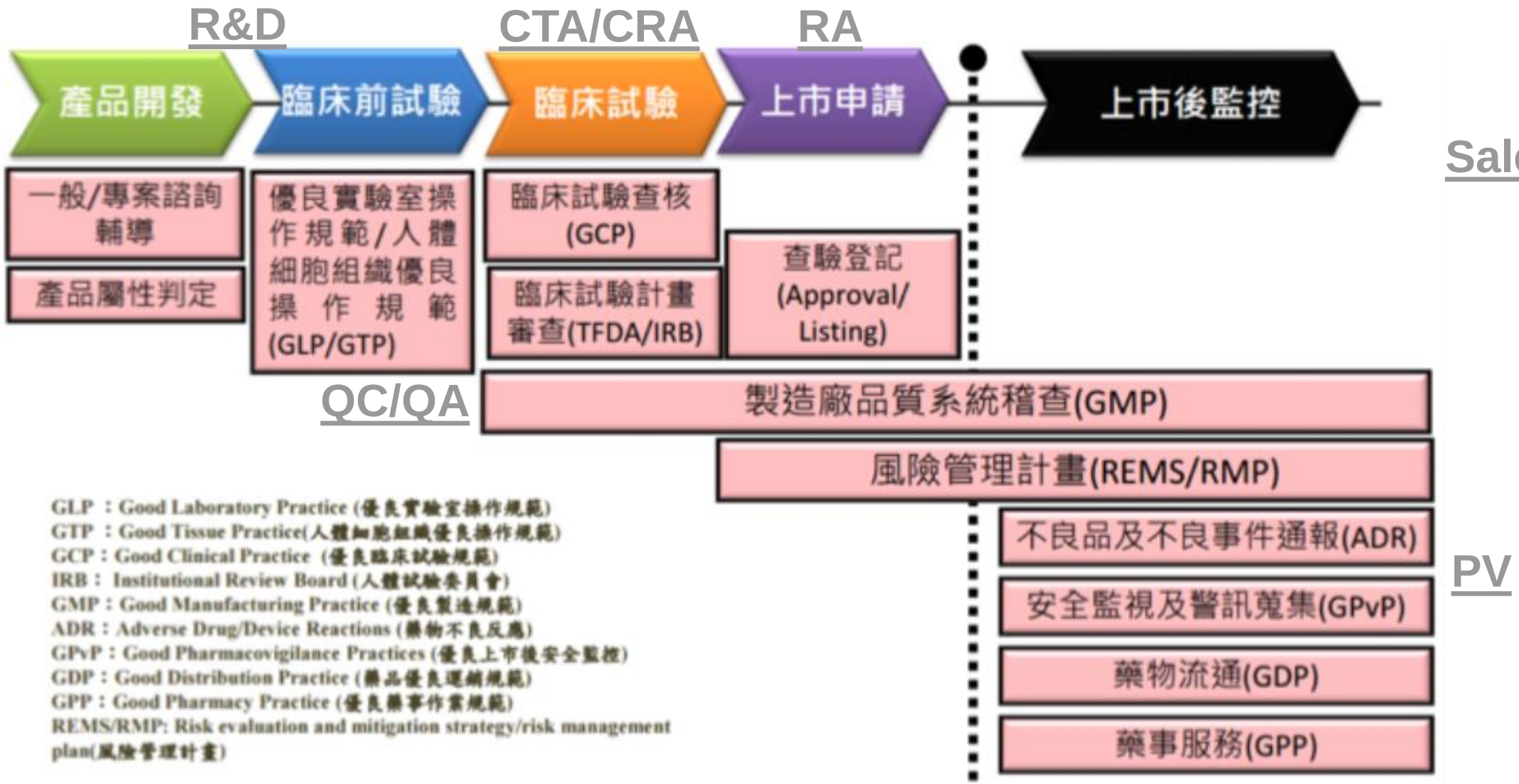
醫藥產業

- 產業界
  - 本土企業
    - 代理商
    - 製造商
    - 醫療服務業
  - 外商公司
    - 製造商
    - 醫療服務業
- 學術界
  - 研究單位

Page 3

醫藥產業

藥物的生命週期管理:目的是為了確保產品的安全性及有效性



GLP ：Good Laboratory Practice (優良實驗室操作規範)
GTP ：Good Tissue Practice(人體細胞組織優良操作規範)
GCP：Good Clinical Practice (優良臨床試驗規範)
IRB： Institutional Review Board (人體試驗委員會)
GMP：Good Manufacturing Practice (優良製造規範)
ADR：Adverse Drug/Device Reactions (藥物不良反應)
GPvP：Good Pharmacovigilance Practices (優良上市後安全監控)
GDP：Good Distribution Practice (藥品優良運銷規範)
GPP：Good Pharmacy Practice (優良藥事作業規範)
REMS/RMP: Risk evaluation and mitigation strategy/risk management plan(風險管理計畫)

- 語言能力
- 團隊合作
- 溝通協調
- 開放的心態

Thank you for your attention

Delivering growth – in Asia and beyond.

Q and A

研發工程師 (R&D)

研發工程師 03/04更新

聯華生技股份有限公司　本公司其他工作

工作內容

1.檢測試劑產品開發、性能評估規劃與驗證
2.產品技術、品質管制及法規相關文件撰寫製作
3.經銷商及客戶端技術支援
4.研發計畫執行與報告撰寫
5.外部合作對象接洽與溝通
6.一般行政作業及主管交辦事項

職務類別　實驗化驗人員、生物科技研發人員

生醫研發工程師 03/12更新

台灣共振波研發股份有限公司　本公司其他工作

工作內容

工作內容
1.協助執行相關臨床前或臨床試驗研究，如: 動物行為測試，生化分析及細胞培養。
2.協助執行產學合作計畫。
3.協助公司醫材產品之開發。
4.協助試驗數據分析整理、學術論文資料蒐集及撰寫相關報告。
5.其他主管交辦事項

品管/品保人員 (QC/QA)

QA 品質部-資深專員(LT) 03/18更新

台灣大昌華嘉股份有限公司　本公司其他工作

工作內容

1. 協助廠內外稽核作業。
2. 其他品質管理事務，例如：客訴/異常/變更/認證申請..等相關作業。
3. 文件管理作業，例如品質文件管理包含歸檔、發行..等。
4. 協助廠內專案執行。

職務類別　ISO / 品保人員、品管 / 品保工程師、品管 / 檢驗人員

抗體藥物分析品管人員 03/18更新

中裕新藥股份有限公司　本公司其他工作

工作內容

1. 分析方法轉移、確效
2. 抗體藥物分析實驗、生化方法分析。
3. 安定性計畫與委外實驗室管理
4. 具GMP藥廠原料檢驗、方法確認(method verification)經驗者佳。

職務類別　品管 / 檢驗人員、生物科技研發人員、醫藥研發人員

臨床試驗專員(CTA/CRA)

臨床研究部-研究助理(CTA)/專員 03/05更新

康霈生技股份有限公司 本公司其他工作

工作內容

1. 臨床試驗送審資料準備與送件
2. 臨床試驗相關資料整理歸檔
3. 溝通協調臨床試驗相關事宜
4. 新藥資料與文獻收集整理
5. 部門行政庶務
6. 主管交辦事項

*良好外語溝通協調技巧、可獨立與國外廠商溝通協調。
*具備臨床研究相關知識例如GCP和IRB送件。

臨床試驗專員 (Clinical Research Associate, CRA)

精睿醫藥科技股份有限公司 本公司其他工作

工作內容

1. 臨床試驗法規審查資料準備與送件
2. 與試驗團隊聯絡及問題之溝通協調
3. 臨床試驗執行與收案進度追蹤
4. 臨床試驗監測與試驗品質控管
5. 臨床試驗相關資料整理歸檔
6. 其它交辦事項

職務類別 醫藥研發人員、病理藥理研究人員、生物科技研發人員

法規人員(RA)

Sr. Regulatory Affairs Specialist

美敦力 · 台灣 Taipei City 台北

刊登日期: 2 週前 · 81 位訪客

應徵 儲存

Careers that Change Lives

A Day in the Life

Responsibilities may include the following and other duties may be assigned.

- Directs or performs coordination and preparation of document packages for regulatory submissions from all areas of company, internal audits and inspections.
- Leads or compiles all materials required in submissions, license renewal and annual registrations.
- Recommends changes for labeling, manufacturing, marketing, and clinical protocol for regulatory compliance.
- Monitors and improves tracking / control systems.
- Keeps abreast of regulatory procedures and changes.
- May direct interaction with regulatory agencies on defined matters.
- Recommends strategies for earliest possible approvals of clinical trials applications.

parexel

Regulatory Affairs Consultant

百瑞精鼎國際股份有限公司 · 台灣 Taipei City 台北 1 個月前

應徵 儲存

Job Description

- Works effectively within a team environment but may work independently delivering services within their area of competence
- Works within broad project guidelines as directed by the project team
- Takes initiative to prioritize work to achieve specified project outcomes while confirming alignment with project team
- Produces quality work that meets the expectations of project lead and the client
- Completes assigned activities within project scope and objectives with an understanding of issues which may impact project profitability
- Proactively assesses client needs and develops processes and solutions to address issues
- May manage small to large scale projects
- May participate in project scoping calls and/or proposal preparation with the support of senior colleagues

藥物安全監視專員 (PharmacoVigilance Specialist)

PV Associate / Senior PV Associate 03/04更新

台灣安斯泰來製藥股份有限公司　本公司其他工作

- ICSR Case intake and local process
- Local PV Quality Management System
- Risk Minimization Plan (RMP)
- People and Organization Management

Individual Case Safety Report, ICSR

Pharmacovigilance Specialist

昆泰 · 台灣 Tainan City Dawan

刊登日期: 1 週前 · 255 位訪客

Essential Functions

- Performs safety case processing tasks including, but not limited to: Intake and triage tasks as performed by Clinical Safety Associate and/or Senior Clinical Safety Associate.
- Reviewing incoming safety information for completeness and accuracy.
- Tracking and data entry Writing clinical narratives Generating queries.
- Contacting sites for missing and/or unclear information QC of cases.
- Generating regulatory reports Reconciliation Generating metrics.
- Serve as Safety Management key contact point on moderate to large sized studies/programs that are moderate to complex in scope of work with minimal guidance.
- All aspects of Safety Management start-up process including writing Safety Management Plan, developing SAE form, etc.
- Attendance at team, client and investigator meetings
- Presentations Training of staff on safety processes
- Compliance with budget, including estimating monthly budget projections.
- Ensures compliance with client budget and proactively escalates potential scope changes or noncompliance with cost or time allocation to department managers
- May assist with bid defenses or other presentations
- May mentor and/or train new Safety Management staff Performs other related duties as assigned or requested by department management

業務代表(Sales)/產品經理(PM)

[Janssen] Sr. Professional Sales Representative

強生公司 · 台灣 Taipei City 台北

刊登日期：2 週前 · 355 位訪客

Job Description

Responsible for promoting our pharmaceutical products to the healthcare professionals with the aim to bring our innovative treatment solution to our patients.

Key Accountabilities

- Creates a plan to achieve objectives through sales and servicing of all hospital accounts in a prescribed territory.
- Make regular visits to identify customers' needs, provide treatment solution to HCP, and gather information on orders and market conditions.
- Prepares sales reports and documents as required.
- Follows up with customers to resolve any issues and ensure satisfaction.
- Develops and maintains sales forecast and submits to management.
- Relays relevant market information to management.
- Conduct product listing.
- Collaborates with other departments to achieve company objectives and ensure a timely resolution.
- Initiates contact and schedules appointments with customers.
- Identifies/analyzes potential opportunities to business.
- Recommends areas for future growth.
- Complies with Integrity and compliance standard.

Product Manager

荷商葛蘭素史克藥廠 • 台灣 Taipei City 中正區

刊登日期：2 天前 · 84 位訪客

Key Accountabilities / Responsibilities

This role will provide YOU the opportunity to lead key activities to progress YOUR career. These responsibilities include some of the following:

 New product launch strategy and operational planning
 Join plan session with cross functional team with Market Access/Medical, Regulatory, Region/Global to have launch excellence
 Formulate and implement product marketing goals, strategies, plans and programs to ensure share of market and profitability of products.
 Organise and execute the overall product marketing activities and programs such as symposium, forums and overseas congress etc.
 Ensure effective control and monitor of marketing results within designated budgets.
 Prepare and implement product promotion expense budgets.
 Develop and implement product knowledge training and product communication tools (detailing pieces. Patient education kits).
 Analyse competitive position of company products and recommend price structures.
 Establish solid rapport and specialised presentation to key customers
 Conduct market research programs. Supervise and co-ordinate advertising programs and PR events.
 Communicate with field forces on sales campaigns and marketing activities and monitor follow-through
 Prepare product forecast for adequate stock
 Review and approve the artwork for post approval variation in labeling or CMC change including providing data to support the PSR submission and also align with artwork management SOP. And perform L1 monitoring of artwork process and activities within their area of responsibilities.