Global Allied Pharmaceuticals, LLC.

A Brick and Mortar Company; 1687 associates worldwide, and growing. We have been the premier subcontractor to the largest BPO's of the world in the past 9 years.

Introduction to GAP (Global Allied Pharmaceuticals)

- GAP is a full turn- key strategic consulting, 1600+ Full-Time Employees in 49 countries with offices in N. American, Latin America, Common Wealth of Russia as well as India.
- The Business Processing Organization(BPO), Contract Research Organization (CRO), and Contract Development Manufacturing Organization(CDMO) company wrapped.
- GAP provides entire gamut of Drug Development Services to the Pharmaceutical, Biotechnology and Medical Device Companies.

Our Mission

GAP is committed to support you to meet the global challenges of drug development process through quality scientific research services. Cost containing measures without compromise of quality and ready to scale up in a very short period of time as a vendor

Services

- Clinical development
- Due-Diligence
- Drug Safety and Pharmacovigilance
- IT services
- Legal
- Medical monitoring
- Medical writing
- Medical Affairs
- Medical marketing
- Mergers and acquisitions
- Regulatory and quality services
- Strategic consultancy
- Trial acceleration
- Technical augmentation
- Technology transfer

Clinical Development

Clinical development Phase II and Phase III are a major challenge in terms of cost and attrition rate. They can be achieved with GAP's help through proper conduit and continuous training.

GAP has a team with therapeutic, regulatory, and operational expertise.

GAP provides the following services as a part of clinical development:

- Steering Committee Development
- Central IRB/Ethic Management
- Site Management
- Clinical Trial Development and Operations
- Notifications and Equipment removal
- Accrual and Recruiting Boost
- Clinical Safety Services
- Clinical Affairs

Clinical Development

GAP has a team with therapeutic, regulatory, and operational expertise.

GAP provides the following services as a part of clinical development:

- Provides 24/7 medical monitor services with lead and junior level MD, medical experts.
- Both remote and onsite technical services with Clinical Research Associate, and project managers.
- All other aspects of clinical operations support and medical/clinical expertise.

Accelerating Clinical Patient Recruitment

- GAP has a team of MD physicians with focussed patient accrual.
  - The driving force for patient recruitment of GAPs ability facilitate enrolment in clinical trials is our relationship with clinical trial investigators and research staff.
  - Patients recruited to participate in cancer clinical trials are generally informed about the existence of the trial by a participating investigator.
  - providing ongoing support to clinical trials through site visits, weekly phone calls, and email.
  - working directly with investigators and research staff to identify strategic actions to overcome these barriers
  - GAP understands that open communication with investigators and research staff is critical to keeping clinical trial enrolment "top-of-mind" with investigators.

Due-diligence

Goals and Ambitions

- We understand the business goals. We review the matter from every possible angle; including but not limited to legal, scientific and economics.
- We evaluate the degree to which components of the target IP will satisfy each of those goals.
- We will spot the IP issues. A complete mitigation associated with the context of the business, the IP issues, and the definitive answers to the questions will be provided.
- We provide the required effective communication of an evaluation to decision makers by keeping the business goals in mind throughout the due diligence process.

Due-diligence

GAP uses the following to review and evaluate the road map to success

- Material checklist
- Ownership
- Review License Agreements
- Patent Validity
- Claim Scope
- Patent Term and Exclusivity
- Ex-US Filings
- Freedom to Operate
- Enforcement Challenges/Mitigation
- Evaluation of the Trade Secrets
- Compliance with OIG, CIA and beyond

Drug Safety & Pharmacovigilance

- With ever changing regulations, drug safety is an ever evolving sector of biopharmaceutical companies.
- GAP has a team of experts in all associated areas of Pharmacovigilance and drug safety.
- Our services includes, but is not limited to:
  - Case management,
  - QPPV services,
  - Risk management,
  - Medical review,
  - Signal detection,
  - Audit and inspection services,
  - Aggregate reporting and narrative writing
- Engaging from simple reporting of case to preparation of expert report of the drug profile. This is not short-lived, but will be followed through the life cycle of the product.
- Capable to manage the large pool of data and systematically analyze the data as needed.

Information Technology Services

- GAP has a team of experts providing the following services
  - Clinical Data Management and Analysis
  - Brand development with Advertising
  - Complete Website Transformation
  - E-Commerce Solutions
  - IT Consulting
  - Multimedia Services
  - Open Source Customization
  - Portal Development
  - Software Development
  - Search Engine Optimization (SEO)
  - Website Designing
  - Website Development
  - Web Solutions

Legal Services

- GAP has a team of experts providing the following services
- We have been the sole supporting entity for the top 25 small and medium size companies over the last year along.
- GAP provides the most innovative and mitigating remedies to the most complexes challenges in the industry.
- We are not just a group of legal scholars, but we are a group of legal advocates.

Medical Monitoring

- GAP has a team of experts both clinical and research experience, and some serve as academic investigators.
- Uses practical knowledge and experience to present solutions for the issues that occur in clinical research studies.
- Expert physician on panel can serve as a link for investigators with primary aim to accelerate timelines and productivity.
- GAP provides the following services under medical monitoring:
  - Risk based monitoring
  - Regulatory services
  - Safety & medical monitoring
  - Clinical monitoring/ site management
  - Asset management/development

Medical Writing

- GAP has a team of experts provides services but not limited to
  - **Regulatory Document:** New Drug Applications (NDA), Investigational New Drug Application(IND), Protocols(Preclinical as well as Clinical) including but not limited to Investigators Initiated Trials, and/or Investigators Brochure.
  - **Safety aggregate report:**
    - Package Insert, patients' letter, etc.
    - Clinical Trial Report /Clinical Study Report–Phases I- IV.
    - Patient Document–Informed Consent Document including patient information sheet, patients' pamphlets, etc.
    - Aggregate Reports, (PSUR, DSUR) ad hoc reports, Dear Dr./investigator, etc. communications.
  - **Journal articles:** Original Research Material and publications, Review articles, Editorials, Publication in journals, Submission to medical meetings, Posters including presentation at medical meetings, Advisory boards. Medical education materials like Monographs, Training materials, and/or prescribing information.
  - **Commercial/ Marketing subject matters:** Review Articles, Manuscripts, Case Studies, Conference Abstracts, Slide presentations, Original research, Symposia, Round tables, and marketing material not restricted to Advertisements, Public relations materials, Internet documents.

Medical Affairs

- GAP has a team of experts provides services but not limited to
  - Expertise provided by clinical/industry trained specialists in Medical Oncology, Surgical Oncology and hematology.
- Our critical services in the following areas are at your disposal:
  - **Product Development & Commercialization**: Depict on strategic advancements produced in clinical and commercial endeavours over the past 124 years of this industry.
  - **Market Access**: Construct a spirited worth with our profound expertise in optimizing assessment. Experience powerful market implementation in oncology.
  - **Regulatory & Quality**: Stay in front of continuously evolving regulatory necessities while ensuring your advantageous edge. We have been the trend setters.
  - **Market Intelligence**: Enlarge the superior leadership, advantageous production strategy, creation progress and commercialization with pertinent, and robust market aptitude.

Medical Marketing

- GAP We have acquired Pharma-sales Inc, with the ability and proven track record to launch the top tier/flag-ship products in different therapeutic areas especially in Oncology.
- Sole responsible party for the international launching of products in oncology with global partners as well as the domestic leaders.
- Operates as a separate entity.
- Availability of 500 sales staff/full-fledge who are ready to march into the fields

Mergers and Acquisitions

- As a partner to expedite the success in pharmaceutical development; GAP assures a superior process via:
  - Control the risk across the product lifecycle in your oncology portfolio.
  - Augment capability for growth and profitable operation in ramping up your oncology and hematology production sheet.
  - Therapeutically aligned to provide the most profitable outcome.
  - Enlarge fiscal scenario and profit/loss liberation.
- We are the experts in:
  - Managed Partnerships.
  - Outsourcing.
  - Biotech Relationships.
  - Government & Non-Profit

Regulatory and Quality Compliance

Regulatory Compliance

- GAP provides excellent expertise in global drug and devices development leads us to provide a variety of services in the regulatory area:
  - Global Regulatory Strategies and implementations.
  - Regulatory support of clinical development and operations, marketing, and medical Affairs.
  - Filings and advocacy.
  - Labeling and Representations.
  - Life cycle of documentation management.
  - Filing, Certificates, Approval, and beyond.
  - Turnkey pre and post-marketing regulatory representation of advocacy.

Regulatory and Quality Compliance

Quality compliance

- **GAP provides excellent services of Quality assurance and compliance but not limited to below**

Quality Assurance:

- QA/Quality Control Staff Augmentation
- Policy, SOP & Batch Record Review, Preparation & Optimization
- Quality System (QS) Development, Assessment & Optimization
- Root Cause Investigations & Corrective & Preventive Action (CAPA) Planning & Execution
- Training - FDA, GMP, QSR, DQSA, USP <795>, USP <797>, Validation, etc.

Compliance Services:

- Third-party GMP & GLP Compliance Auditing
- Mock FDA/International Regulatory Agency Inspections & PAI Readiness
- Due Diligence Compliance Inspections, Audits & Assistance
- FDA Action (483 Observations, Warning Letters, Consent Decrees) Remediation

Strategic Consulting

- GAP has extensive experience in designing and conducting oncology studies. GAP's strategic consulting team services include :
  - Optimization
  - Tool Box
  - Planning
  - Validation

Trial Acceleration

- The Trials Acceleration is an exciting initiative by GAP, to deliver more efficient treatments plan in cancer through various tools for the acceleration of clinical trials. We believe in delivering information for the success of clinical trials.

We provide following services as part of trial acceleration:

- Site Recommendation
- Patient Recruitment
- Accrual Workshops
- Community Research Consortium

Technical Augmentation

- GAP provides the proper technology solutions to improve the current pipelines safety and efficacy, solve the everlasting IP challenges, as well as to identify the appropriate venue of products diversification.
- Provide innovative technology to identify the candidate molecules, and its determination of whether the system-level consequences of attempting to intervene in a particular pathway will lead to the desired beneficial outcome.
- The various technical augmentation strategies include:
  - Immuno-Oncology
  - SCP-Technology
  - ADC-Technology

Technology Transfer

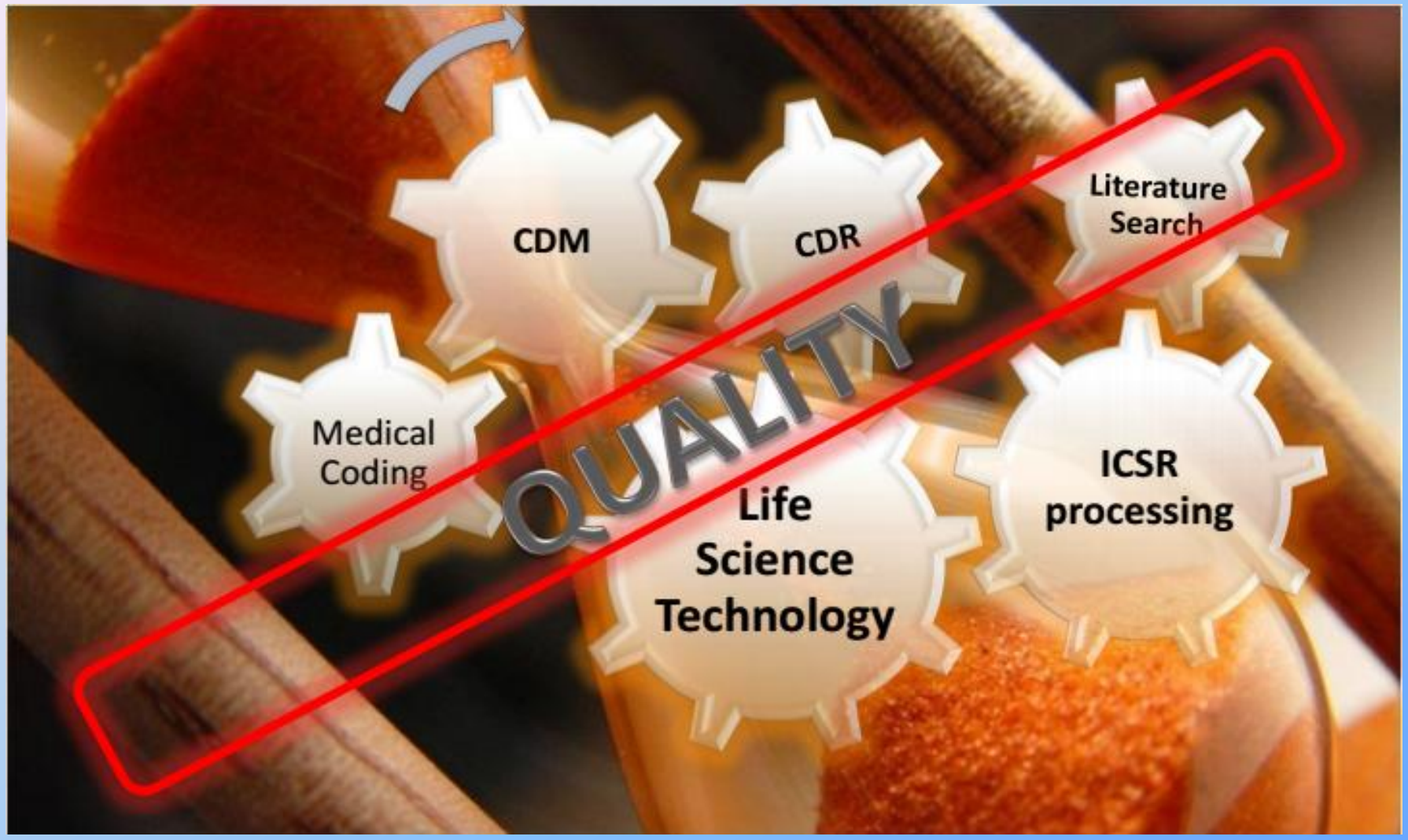
- GAP provides the complete platform of Immune Oncology. Antibody Drug Conjugates, vaccines, and beyond. Visit our master piece at: Immuno-Oncology
- GAP harvests the cutting edge technology of “Antibody Drug Conjugate (ADC)” for you. Visit our show case at: ADC
- GAP would provide a spectrum of advanced CMC solutions to avoid any generics pitfalls.
- GAP has provided pegylations, liposomes, nano- technology in formulations, and conjugates in combination CMC realms among other IP- protected solutions. These are all intended to extend, protect, and potentially expand on your existing IP with a spectrum of clever and protected platforms.
- GAP offers a spectrum of complementary solutions into a full technology and private sector transfer.

Medical Monitoring

Other services includes.

- **Data and Safety Monitoring Board (DSMB)**
  - GAP has provided DMCs that have included proper known opinion leaders and experts.
  - Our established DSMBs have provided their expertise in an efficient and effective fashion with delivering their timely analyses and results.
- **Clinical Events Committee (CEC)**
- **Safety Assessment Committees (SAC)**
  - GAP''s SAC includes a therapeutic leader in the indication of the product, specialists across the specific Therapeutic Areas (TAs) as needed, a core MD/Safety Lead which allows regular and ad hoc meetings.
  - It may be structured as an internal, external (as highly recommended by FDA), or both, as needed. Its compliance is priceless.

GAP : Why ?


CDM
CDR
Literature Search
Medical Coding
QUALITY
Life Science Technology
ICSR processing

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