PharmaMed Resources, LLC

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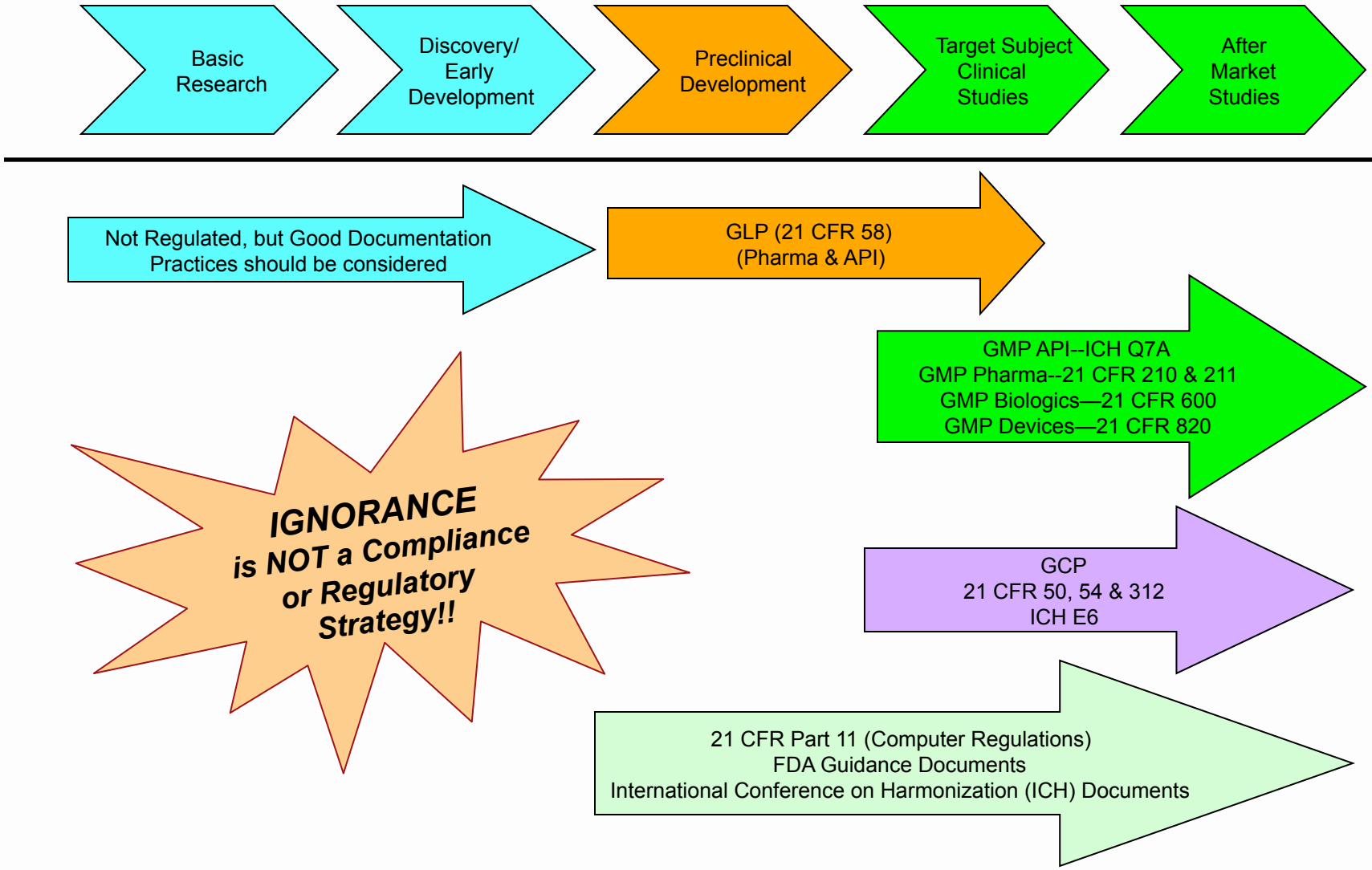
Good Practices Related to Development



Policy and Procedure

- Quality Systems and client-specific policy / program development
- Standard Operating Procedure (SOP) development
- Device Master Record development / preparation
- Pharmaceutical Master Batch Record development / preparation
- On-site implementation of policy and procedures available

Regulatory Documents and Submission

- Facility registration assistance
- Device registration assistance
- 510(k) application preparation
- Premarket Approval (PMA) application preparation
- Investigational Device Exemptions (IDE) preparation
- CE Mark consultation including technical file preparation
- 483 and Warning Letter response assistance
- Preparation of Investigational New Drug Applications (IND)
- Coordination of NDA and ANDA documents
- Coordination of EU Clinical Trial Authorization (CTA)
- Coordination of other regulatory documentation for world-wide registration
- Clinical label consultation including label review and approval

Training

- 21 CFR Part 210, 211 and 820 cGMP compliance training
- EU (IVDD, MDD and Pharmaceutical) compliance training
- Client-specific policy and procedure training

Auditing and Validation

- 21 CFR Part 210, 211, 820 and EU GMP client internal audits
- 21 CFR Part 210, 211, 820 and EU GMP client - vendor / contractor / partner audits
- IVDD (98/79/EC) and MDD audits
- Client internal procedure compliance audits
- FDA and EU Labeling compliance assessment
- Facilities, equipment and computer validation
- Due diligence investigation of potential partner companies/contract vendors
- Experienced in auditing of all types of manufactured dosage forms, laboratories, packaging and label operations, utilizing GxP, CAP and CLIA regulations as requested by client.

Oversight

- FDA U.S. Agent representation
- Third party Batch Record Review
- Third party Device History Record Review
- Contract functional group / department head manager
- Contract project management
- Point of contact between client and partner companies
- Quality Agreement preparation and negotiation
- Contract Vendor manufacturing batch record pre-approval and review
- Contract Vendor packaging and labeling batch record pre-approval and review

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www.pharmamedresources.com
A member of the Michigan CMC Alliance
www.micmcalliance.com

Who is the FDA? (www.fda.gov)

- An agency of the United States Department of Health and Human Services
- Responsible for the safety and effectiveness regulations for food, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products and cosmetics
- Establish and enforce high laboratory standards, product standards, and ethical clinical practices, plus other regulatory requirements

Good Clinical Practice
ICH E6 Good Clinical Practices
21 CFR 50 & 56

- An internationally (EU, US, Japan) harmonized ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.
- Good Clinical Practice Guidelines include standards on how clinical trials should be designed, conducted, defines the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors.
- Govern all clinical studies that could affect the safety and well-being of human participants.

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Good Manufacturing Practices
21 CFR 210 and 211 (pharma)
21 CFR 820 (device)

- FDA Regulations that represent the minimum requirements that govern the pharmaceutical and medical device industries.
- The GMP's provide guidance to ensure that a drug product or device is safe & effective for human or animal use and meets the quality and purity characteristics attributed to it.
- Used during the preparation (mfg and pkg) of clinical trial materials (CTM's) to be administered in human/ target animal clinical studies
- Used by Laboratories that support the manufacture/ testing/packaging of the CTM's
- In preparation of components that are used in CTM's
- In the preparation of Active Pharmaceutical Ingredients that are used in CTM's.

Good Laboratory Practices
21 CFR 58

- FDA Regulations that govern the organization, process and conditions under which laboratory studies are planned, performed, monitored and reported.
- Used for non-clinical safety studies supporting the development of drugs and devices.
- Agricultural pesticide development
- Development of toxic chemicals
- Food control (food additives)