Sharlene L. Lucio

Clinical Trials and Batch Records - items not addressed in my resume'

Clinical Trials Coordinator – Experienced and motivated. Conducted clinical research studies in clinical research setting for listed companies below.

1) Created a list of questions to be asked during the clinical trials,
2) Designed clinical trail matrices
3) Commandeered multiple physicians to perform clinical aspects of clinical trails
4) Coordinated clinical trials data and recorded technical data
5) Transcribed physician's notes for FDA data submissions and approvals
6) Scheduled locations, scheduled participants appointments and payments
7) Purchased Personal Protective Equipment - PPE
8) Recruited clinical candidates
9) Identified gaps and opportunity for areas of improvement
10) Recorded personal data and clinical information
11) Confidential Clinical information quality controlled

Integra Life Sciences, PA (ALKU Consulting) **07/2018 – 12/2018**

Endo Pharmaceuticals, PA (Spectraforce Technologies) **03/2015 – 03/2016**

Agile Department Manager, Oraya Therapeutics, CA **06/2008 – 08/2011**

BMRs - Batch Manufacturing Records -

GMP support to manufacturing batch records

1) Wrote FDA requirements and documented details of executed processes
2) Documented "how to create the product" - start to finish processes
3) Tools – documented materials, steps and equipment
4) Harmonized GMP requirements
5) MFR – Master Formula Records
6) Documented test methods and confidential Logbooks

Immunomedics, NJ (American Contracting Group) **10/2017 – 06/2018**

Veeva Vault Change Coordinator MAP Pharmaceuticals, CA **03/2012 – 07/2013**

Agile Document Manager, Allied Telesyn Inc., Sunnyvale, CA **05/2000 – 07/2006**