Colorado SIP Amended Appendices List[1]
December 4, 2025

A. SIP Sponsor

a. Name of Sponsor, Address, Responsible Individual(s)
b. Attestations/Conflict of Interest Forms for Responsible Individuals
   i. Kelly Swartzendruber
   ii. Vincent Giglierano
c. Vendor Quality Manual* V4 - 5105-1
d. Quality Agreement*
e. Vendor Standard Operating Procedures*
   i. HCPF Regulatory Inspections 5079-1
   ii. HCPF Internal Audit Procedure 5080-1
   iii. Non-Conformance Procedure 5081-1
   iv. Corrective and Preventive Action Procedure - 5082-1
   v. HCPF Planned Deviation Procedure - 5083-1
   vi. HCPF Documentation Control - 5084-1
   vii. Procedures for SOPs 5085-1
   viii. Partner Qualification Audit Procedure V3 5086-1
   ix. HCPF Management Review - 5088-1
   x. HCPF Customer Complaint Procedure V2 - 5089-1
      1. Colorado Drug Importation Program Case Handling (COI SOP 4796-1)
      2. Colorado Drug Importation Program Transmission and Reconciliation (COI SOP 4797-1)
   xi. HPCF Record Retention and Disposition Procedure V3 - 5090-3
   xii. HCPF Compliance Management and Tools 5091-1
   xiii. HCPF Record Digitization 5092-1
   xiv. HCPF Training 5096-1
   xv. HPCF Risk Management - 5098-1
   xvi. Partner Safety Report Recognition & Reporting 5099-1
   xvii. Drug Evaluation 5180-1
   xviii. Materials Training Form 5195-1
f. Partner Checklists
   i. Foreign Seller
   ii. Importer
   iii. Qualified Lab

B. Foreign Seller

[1]Updated documents are highlighted in blue font. Documents in black font were not submitted on December 4, 2025 and were submitted to FDA on March 10, 2025, August 28, 2024 and/or February 27, 2024.

a. Name of Foreign Seller, Address, Responsible Individuals
b. Attestations/Conflict of Interest Form
c. Certifications/Registrations -FDA and Website
    i. Drug Establishment Listing
    ii. Health Canada Inspectional History for Last 5 Years
    iii. FDA Foreign Seller Registration
d. Vendor Standard Operating Procedures*
    i. SOP-SIP 001 Labeling
    ii. SOP-SIP-002 Pre-Import Process
    iii. SOP SIP 002 Form
    iv. SOP SIP 002 Shipping Transfer
    v. SOP SIP 003 SIP Reporting
    vi. SOP SIP 004 Recall of Product
    vii. SOP SIP 004 Product Form
    viii. SOP SIP 005 Supply Chain Security
    ix. SOP SIP 018 Receiving, Storage, Pick, Pack, Shipping

C. Importer

a. Name of Importer, Address, Responsible Individuals
b. Attestations/Conflict of Interest Forms/Confidentiality Agreements (AdiraMedica LLC. & Q Labs)
c. AdiraMedica LLC. Pennsylvania License, Registration, & Inspectional History, Colorado Wholesale License, FDA WDD Reporting
d. Relabeler Name, Address, Registration
e. Qualified Lab Inspection History, Certifications, FDA Registrations
f. Q Laboratories/AdiraMedica LLC. Quality Agreement
g. AdiraMedica LLC. and AdiraMedica Inc. Quality Agreement
h. Pharmacovigilance Agreements
    i. Pharmacovigilance Master Services Agreement (MSA)
    ii. Safety Data Exchange Agreement (SDEA)
i. Vendor Standard Operating Procedures*
    i. SOP-900 Rev 00 EFF 31OCT25 - Receipt of Imported 804 Drug Product (SIP) - Final and related FORMs
    ii. SOP-901 Rev 00 Eff 03DEC25 - Sampling and Statutory Testing (SIP) - Final
    iii. SOP-902 Rev 00 Eff 24NOV25 - Recall of Imported Drug Products (SIP) - Final and Forms
    iv. SOP-903 Rev 00 Eff 24NOV25 Lot Disposition for Relabeling (SIP) - Final
    v. SOP-904 Rev 00 Eff 02DEC25 - Inventory Management & Disposition
    vi. SOP-905 Rev 00 Eff 03DEC2 - Relabeling for U.S. Distribution (SIP) - Final
    vii. SOP-906 Rev 00 EFF 17NOV25 - Training Program (SIP) -Final and Related Forms

viii. SOP-907 Rev 00 EFF 07NOV25 - Pre-Import Request Process SIP - 31Oct25 Final and Related Forms
ix. SOP-908 Rev 00 EFF 07NOV25 - Importation of Canadian Products (SIP) - Final
x. SOP-909- Rev 00 Eff 31OCT25 - NDC Number Assignment (SIP) - Final and related Form approved
xi. SOP-910 Rev 00 EFF 07NOV25 - Reporting of Canadian Imports (SIP) - Final and related Form
xii. SOP-911 Rev 00 EFF 01DEC25 - Drug Supply Chain Integrity (SIP) - Final and related Forms
xiii. SOP-912 Rev 00 EFF 07NOV25 - Field Alert Handling (SIP) Imports - Final and Related Forms
xiv. SOP-913 Rev 00 Eff 10NOV25 - Adverse Event Handling (SIP) - Final and Related Forms
xv. SOP-914 Rev 00 Eff 21NOV25 - Return Process Plan (SIP) - Final and Forms
xvi. SOP-915 Rev 00 Eff xx Product Complaint Handling (SIP) - Final and Forms
xvii. SOP-916 Rev 00 EFF 17NOV25 - Item Master Specification (SIP) -Final and related Forms
xviii. SOP-917- Rev 00 Eff 01DEC25 - Batch Record Documentation (SIP) -Final
xix. SOP-918 Rev 00 EFF 17NOV25 - Destruction of SIP Product - Components -Final and Related Forms
xx. SOP-919 Rev 00 EFF 07NOV25 - Inspection of SIP Products - Materials - Final and Related Forms
xxi. SOP-001 Rev 12 Eff 31OCT25 - Creation and Maintenance of SOPs Forms and WI - Final
xxii. SOP-013 Rev 10 EFF 08Nov24 Corrective Action and Preventative Action - OFFICIAL
    1. FORM-013A Rev 02 EFF 08Nov24 CAPA Record - OFFICIAL
    2. FORM 013B Rev 01Eff 29SEP23 - CAPA Log - OFFICIAL
    3. FORM-013C Rev 01 EFF 08Nov24 CAPA Extension - OFFICIAL
    4. FORM-013D Rev 00 EFF 08Nov24 CAPA Effectiveness Check Report - OFFICIAL
xxiii. SOP-016 Rev 07 EFF 18SEP23 - Change Control
    1. Form 016A Rev01 Eff 9-18-23 Change Control Request Log
    2. Form 016B Rev 03 Eff 19Sep24 Change Control Request
xxiv. SOP-022 Rev 04 EFF 24Nov25 Quality Risk Management
    1. FORM-022A Rev 00 EFF 24Nov25 Quality Risk Assessment
    2. FORM-022B Rev 00 EFF 24Nov25 QRA Number Assignment Log
xxv. SOP-025 Rev 11 EFF 30JUN25 - Temperature and Relative Humidity Monitoring - Final

xxvi. SOP- 039 Rev 08 EFF 08SEP25 - Vendor Assessment and Approval Process - Final
    1. FORM-039A Rev 00 EFF 08SEP25 - Non GMP GDP Vendor Qualification Questionnaire - Final
    2. FORM-039B Rev 00 EFF 08SEP25 GMP-GDP Vendor Qualification Questionnaire - Final
    3. FORM-039C Rev 01 EFF 31OCT25 - GMP Vendor Qualification Questionnaire - Final
    4. FORM-039E Rev 00 EFF 08SEP25 - Re-Qualification Vendor Risk Assessment - Final
    5. FORM-039F Rev 00 EFF 08SEP25 - Vendor Qualification Memo - Final

xxvii. SOP-060 Rev 00 EFF 30OCT23 - Investigations and Root Cause Analysis - Final - OFFICIAL
    1. FORM-060A Investigation Report Rev 01 EFF 21Jul25
    2. FORM 060B Rev 00 Eff 10-30-23 Investigation Report Log

xxviii. SOP-061 Rev 00 Eff 19 Jul 24- Document Retention
    1. FORM-061A - Rev 01 Eff 29Sep25 - Archiving Box Content List
    2. FORM-061 B Rev 00 Eff 19 Jul 24 -Storage Box Number and Expiry Date Assignment Log
    3. FORM-061 C Rev 00 Eff 19 Jul 24- Record Disposition and Destruction

xxix. SOP-077 Rev 00 EFF 11AUG25 - Quality Management Review - Final
    1. FORM-077A Rev 00 EFF 11AUG25 - Quality Management Review Meeting Agenda - Final
    2. FORM-077B Rev 00 EFF 11AUG25 - Quality Management Review Meeting Minutes - Final

xxx. SOP-083 Rev 00 Eff 11AUG25 - Non-Conforming Report- Final
    1. FORM-083A Rev 01 - EFF 20AUG25 Non-Conformance Report - Final
    2. FORM-083B Rev 00 - EFF 11AUG25 - Non-Conforming Material Report Log - Final
    3. FORM-083C- Rev 00 EFF 11AUG25 - Vendor Corrective Action Report - Final
    4. FORM-083D Rev 00 - EFF 11AUG25 - QC HOLD Tag -Final

j. Pharmacovigilance Standard Operating Procedures (SOPs) & Work Instructions(WI)s*
    i. Pharmacovigilance Case Intake – 5107.3
    ii. Pharmacovigilance Aggregate Reporting – 5109.3
    iii. Pharmacovigilance Downtime Handling of Adverse Events – 5110.3
    iv. Pharmacovigilance MedDRA Coding Conventions and Dictionary Management – 5111.2
    v. Pharmacovigilance Quality Oversight – 5112.2

vi. Pharmacovigilance Training – 5113.3
vii. Pharmacovigilance Escalation of Safety Issues – 5118.3
viii. Pharmacovigilance Safety Data Exchange Agreements – 5121.2
ix. Pharmacovigilance Product Quality Complaints – 5123.3
x. Pharmacovigilance Handling of Medical Information Inquiries - 5124.2
xi. Pharmacovigilance Reconciliation – 5580.2
xii. PV Outbound Communication Attempts - 5623
xiii. PV Business Continuity Plan – 5630.1
xiv. Pharmacovigilance Training Requirements by Job Function – 4414.4
xv. Pharmacovigilance Training Verification Form – 4421.4
xvi. MIQ Work Instruction 2543.13

D. Final Drug List

a. FDA Data List for All 20 Drugs
b. Labels for FDA Per drug
i. Cover Page
ii. Current FDA Approved Package Insert
iii. Current Canadian Monograph
iv. Proposed Package Insert
v. Annotated Label Comparisons
vi. Proposed Package Label
vii. Orange Book Verification

E. Actuarial Cost Savings Analysis

F. Certification Reports

a. Foreign Seller
b. Importer/Relabeler
i. Adverse Event Reporting Partner - new
c. Lab

G. Enlarged Figure Library

a. Figure 2. Detailed Movement of Prescription Drugs
b. Figure 5. Legal Relationships
c. Figure 14. DSCSA Compliance
d. Figure 15 - SIP Drug Recall Map

H. **FDA Correspondence**

a. Guidance Request Letter 2022
b. FDA RFI to Colorado 3/2/23
c. Colorado Intent to Respond RFI 3/23/23
d. CO letter to FDA 5/17/23
e. Meeting Minutes from 6/16/23
f. Colorado letter to FDA 9/5/23
g. Manufacturer responses to Colorado (9/5/23)
h. FDA Response to Colorado 10/27/23
i. Colorado Response to FDA 10/30/23
j. HCPF to FDA Questions 11/29/23

k. FDA Response to Questions 1/22/24

I. Stakeholder Engagement

a. RFI Results
b. Consumer Survey Results
c. Stakeholder Meeting 1/10/23

*These documents describe internal processes and procedures that include security (building and system) information that is exempt from disclosure under Colorado Revised Statutes 24-72-204(2)(a)(VII)(A) and specialized and proprietary information on business operations that are trade secrets exempt from disclosure under 24-72-204(3)(a)(IV).