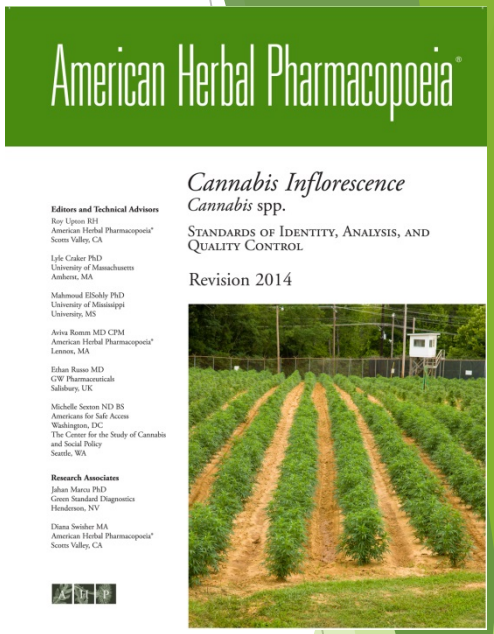
Quality Assurance testing under WAC 314-55-102

RJ Lee Group, Inc.

RJ LEE GROUP
DELIVERING SCIENTIFIC RESOLUTION

Development of the Program

- Requirements for GLP Checklist
  - Align with WAC 314-55-102
  - Ensure consistent and valid results
    - Quality management/quality system
    - Premises & buildings
    - Equipment (PPE)
    - Personnel & materials
    - Productions and process control
- Testing based upon *American Herbal Phamacopoeia: Standards of Identity, Analysis, and Quality Control, Revision 2014*



Certification Process

*Average time from application submission to granting of provisional status is 96 days. Average time from provisional to audit is 81 days.

Requirements for each Field of Testing

- Standard Operating Procedure
- Validation Data/Demonstration of Capability
- Proficiency Testing (if applicable)

Fields of Testing

- Required
  - Moisture
  - Potency
  - Foreign matter inspection
  - Microbiological testing
  - Mycotoxin
  - Water Activity
  - Residual solvents
- Optional
  - Terpenes
  - Heavy Metals
  - Pesticides

Audit Program overview as of September 2017

- 1st year: Initial Application review and on-site assessment
- 2nd year: On-site audit
- 3rd year: On-site audit
- 4th year: Documentation review only (on-site audit not required)
- 5th year: On-site audit
- 6th year: Documentation review only (on-site audit not required)
- Major Checklist updates for 2017:
  - Estimation of Uncertainty requirements added
  - Additional Training requirements added
  - Equipment calibration requirements updated
  - Subcontracting requirements added
  - Additional requirements added for Record control
  - Test Report requirements added
  - Additional QC requirements added
  - Internal audit requirement added

Common Quality Program Deficiencies

- Security procedures not included in SOP's
- Instructions on Law enforcement interaction and federal laws not included in SOP's
- Lack of proper safety equipment including spill kits and safety showers
- No documentation of Software validation/verification
- Logbook documentation not completed and reviews not documented
- No process for Approval of suppliers
- Certificates of traceability not available
- Lack of use of secondary containers
- Lack of traceability to NIST standards
- Lack of Procedure for Management reviews

Costs for Certification

- Initial Application: $2,856.88
- 1st year: Two day on-site auditing plus travel and per diem: $6,439.68

Total initial licensing effort is $9,296.56 (+ travel & per diem)

- 2nd year: Two day on-site auditing plus travel and per diem:$6,439.68
- 3rd year: Two day on-site auditing plus travel and per diem:$6,439.68
- 4th year: Application renewal-paper work review only, (no on-site audit anticipated) $1,733.68

**If additional follow-up required for any audit or review the charge will be $156.00 per hour*