# Best Practices in the Herbal Ingredient Supply Chain

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# GACP: Best Practice Seed to Harvest

- **Good Agricultural and Collection Practice**
  - G**A**P: Relevant to farm operations
    - Propagation material (identity; health and cleanliness; purity; organic status; GMO crops)
    - Site selection (fertility; contaminants; location; crop history;
    - Fertilization (choice and identification; application; guidance on both chemical and organic materials (e.g., composted manure)
    - Irrigation (water source and monitoring; irrigation systems; legal conformity)
    - Crop protection and maintenance (cultivation; companion plants; pesticide use)

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# GACP: Best Practice Seed to Harvest

- **Good Agricultural and Collection Practice**
  - G**C**P: Relevant to wild harvest / wildcrafting operations
    - Permits and permission (public vs. private property)
    - Site selection (species habitat; site history; proximity to features of concern)
    - Collection equipment (materials; maintenance and cleanliness; training and safety)
    - Identification (training & experience; local floras as resources; voucher specimens; plant's life phase; substitutes and adulterants; positive ID)
    - Sustainability (ESA compliance; abundance; population stability; propagation and regeneration; habitat stewardship)
    - Timing of harvest

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# GACP: Best Practice Seed to Harvest

- **Good Agricultural and Collection Practice**
  - Post-harvest handling: Relevant to all operations
    - Handling (containers; avoidance of compaction; protection from contamination; temperature and moisture control)
    - Facilities (light; pest control; order and cleanliness; equipment)
    - Washing and cleaning (water supply; drainage; drying; foreign matter)
    - Dehydration (timing; sunlight and shade; temperature control; air circulation; finished moisture content)
    - Cutting and milling (timing; protection of operators; equipment maintenance; temperature control)
    - Packaging (materials; labeling; storage)

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# GACP: Best Practice Seed to Harvest

- **Good Agricultural and Collection Practice**
  - Personnel: Relevant to all operations
    - Training (relevance to tasks; plant identification; hygiene)
    - Safety (clothing; protective gear; environmental factors; tool and equipment)
    - Hygiene (prevention of contamination; toilet facilities; hand washing; personnel health)

# GACP: Best Practice Seed to Harvest

- **Good Agricultural and Collection Practice**
  - Record keeping and retentions: Relevant to all operations
    - Agricultural crop harvest records (propagation materials; crop site; agricultural inputs; water source and irrigation; harvest details)
    - Wild crop collection records (permits and permissions; collection sites; identification procedures; collection details)
    - Post-harvest handling records (facility; equipment; operations: washing, drying, dehydrating, cutting and milling, packaging)
    - Personnel records (training; safety and hygiene practices)
    - Retention samples (representative; labeling; storage; sample correlation at each stage of processing)

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# GMP: Best Practice Harvest to Manufacturing

- **Good Manufacturing Practice**
  - Relevant FDA regulations???
    - 21 CFR 111: cGMP for Dietary Supplement Operations
    - 21 CFR 112: Produce Safety Rules (FDA now has jurisdiction on farms)
    - 21 CFR 117: cGMP for Food Manufacturing Operations / Hazard Analysis and Risk-Based Prevention Control
    - Which apply to herbal ingredient operations?

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# GMP: Best Practice Harvest to Manufacturing

- **Good Manufacturing Practice**
  - Various herbal ingredient operations:
    - Bulk herb supplier for reprocessing / finished product manufacturing ONLY
    - Bulk herb supplier for consumer sale with no further processing
    - Extract manufacturer
    - Extract supplier for reprocessing / finished product manufacturing ONLY
    - Extract supplier for consumer sale with no further processing
    - Etc.

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# GMP: Best Practice Harvest to Manufacturing

- **Good Manufacturing Practice - Key questions:**
  - Should ingredient suppliers conduct "at least one test or examination to verify identity" for each ingredient?
  - If so, how will the supplier's testing be evaluated?
  - Will ingredient buyers support self-regulatory initiatives? Imposition of GMP guidance for suppliers will only be as good as ingredient buyers make it – quality must take precedence over price.

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# Is it time to amend the FDCA (to "open up DSHEA")?

- **Transparency initiatives**
  - Product registry
  - Botanical ingredient cGMP
  - 3rd–party certification
- **Other industry needs / consumer benefits?**
  - Traditional claims (redefine "drug")?
  - Readdress 3rd-party literature in the 21st century (Internet)?
  - NDI date reset/synthetics/clarifications?
  - Parity on 321 (ff)(3)(B)?
  - State preemption?

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# Thank you!


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