

Gates of Quality: A Multi-Stakeholder Perspective

This document emerged from discussions among members of the SHI Quality and Sustainability Working Group. It maps out what it actually takes to produce herbs that meet regulatory quality standards, breaking down the responsibilities and challenges at each level of the supply ecosystem to create greater understanding among the different stakeholders.

Quality testing catches adulteration and contamination at the end of the chain, but it cannot tell you about what happened upstream. A CoA is not a relationship.



Quality assurance during primary processing | photo by Pebani

Introduction

Quality in the herbal products industry is not a problem that any single actor can solve alone. A wild harvester working in difficult conditions cannot implement new handling practices without compensation and training. A processor cannot absorb the cost of rigorous testing without buyers who value and pay for that rigor. A brand cannot justify paying more for quality material when the market rewards the cheapest product on the shelf.

This document seeks to show that quality is only as strong as the relationships and economic realities at each link. Quality testing catches adulteration and contamination at the end of the chain — but it cannot tell you about what happened upstream. A CoA is not a relationship.

The goal of the SHI Quality and Sustainability Working Group is to build the shared understanding that makes better relationships possible: clearer specifications, more honest conversations about cost, and a collective commitment to ensuring that the people and ecosystems at the beginning of the chain are not the ones who bear the greatest burden. Our hope is that having more open conversations about the challenges at each step can lead to fewer rejections and help eliminate expensive remediation. Ultimately we hope these changes allow companies to pay more for quality material.

This document is a high-level summary of the quality risks at each step to enhance communication. AHPA provides detailed and thorough guidelines on implementing Good Agricultural and Collection Practices. In addition, Good Agricultural and Collection Practices (GACP) for Medicinal Plants is an illustrated booklet outlining these practices for producers. See these guides for insight into the best practices to follow and for ways of assessing suppliers. See SHI's Quality Control section for more information on types of lab testing.

Note: Climate disruptions are increasingly impacting quality. While this document does not touch on these impacts, the SHI Quality and Sustainability Working Group is exploring them elsewhere.

The Fundamental Challenge

Quality herb production requires investment at every level of the supply network, yet these costs are often not shared equitably among stakeholders. The current system often expects the cheapest products with the highest certifications — a mathematically impossible combination that puts the entire supply chain at risk.

The solution requires industry-wide recognition that quality costs money, and that those costs need to be shared appropriately rather than absorbed by suppliers who have the least capacity to bear them.

Compensation Cascade



The SHI website provides an overview of the different steps and stakeholders in a plant’s journey from seed to shelf [here](#).

Key Quality Principles at All Steps

All three of these levels will be subject to FDA inspections which may have different types of inspections. Key quality practices to be followed at all steps include:

- Correct identification
- Cleanliness
- Adherence to regulations at all points of commerce (growing region, producing region, sales region) and accurate completion of the corresponding required documentation
- Meet appropriate specifications

STAGE ONE

The Plant and the Ecosystem

Before tracing the herb's journey through the supply chain, it's worth pausing at the beginning with the plant itself, growing in a field or forest. Quality is shaped long before a harvester arrives. The questions asked here set the foundation for everything that follows.

THE CONVENTIONAL QUALITY QUESTIONS

- Is it the right species? Correctly identified?
- Is it wildcrafted or cultivated?
- Is it organic, pesticide-free?
- Was it harvested at the right time for maximum constituents?

THE DEEPER QUESTIONS

- What is the population status of this plant? Is harvesting at current levels sustainable for the ecosystem?
- Is it on a watch list — CITES, IUCN Red List, and equivalents in other geographies.
- What is the soil health and biodiversity of where it was grown? Organic certification tells you about pesticides, not about soil life.
- What would quality sourcing look like from the ecosystem's perspective?



STAGE TWO

Producers

Producers include wild harvesters and farmers. The main quality principles of Good Agricultural Practices are:

PREVENTION OF CONTAMINATION

From soil or irrigation water, dirty containers, drift from other locations, etc.

BEST ACTIVE INGREDIENTS

The location of the cultivation site (soil and weather influences), the variety of the species used, the irrigation cycles, the harvest time are some of the factors that may influence the potency of the active ingredients.

DOCUMENTATION & TRACEABILITY

If it is traceable then it becomes much easier to identify and therefore address any quality related issues that may arise at a later date. Good record keeping is a major focus of GACP guidelines.

a. Wild Harvesters

THE CHALLENGE

Wild harvesters often live in rural areas with few facilities and resources for proper handling practices. They likely harvest the plants in challenging circumstances, in the hot sun, in the cold, with mosquitos, far from roads. They are often far from running water, either for drinking or washing. They must then carry the sacks of roots and herbs for some distance. The work is difficult. Paperwork can be burdensome and overwhelming. While these communities have developed ways to manage these challenges that are passed down, new quality standards require newer handling practices. Those new to harvesting may lack training in best practices.

QUALITY STEPS WILD HARVESTERS CONTROL

- **Identity verification** — ensure correct species and plant part harvested at the correct time for the life cycle of the plant (season/age).
- **Clean collection practices:**
 - Collect the plant from a clean environment (far from runoff, pesticide drift or other sources of possible contamination).
 - Wash hands, etc.
 - Transport the plant in clean containers, new sacks, clean trucks, etc. without mixing species.
- **Point-of-harvest documentation/traceability**
- **Follow responsible & sustainable harvest practices** for each species, adhere to applicable permits and regulations (i.e. CITES, state and national regulations etc.).
- If wild harvesters are far from processing centers, they may also dry and cut or mill the material themselves. This requires additional quality challenges around good drying practices including ensuring a clean drying location, good air flow to prevent mold, free of pests, etc. Out of necessity, field dried materials are often dried in the sun, which can break down essential constituents, affecting the quality of a finished product.

DEEPER QUALITY QUESTIONS

- 1.What is the harvester actually paid?
- 2.What does a living income look like in this region? Is what they're paid above or below that line?
- 3.Is generational harvesting knowledge honored & compensated?
- 4.Do they know who uses these herbs and why?
- 5.What happens in a drought, or a price collapse and there is no longer a market for these species?

b. Farmers

Recent research has found at least 3,200 species in commercial cultivation. These numbers include all sizes of farms, from one hectare plots to several hundred. Cultivated herbs could be collected from a number of smallholders growing on 1 acre plots in India, consolidated by an aggregator, then sold, or grown in large monocrop fields. It is difficult to generalize the quality challenges farmers face since those challenges will depend on the types of practices followed. At a minimum, to produce high quality plant material, the farmers must ensure the following steps:

THE CHALLENGE

Farmers face contamination challenges that are often outside their direct control: non-point pesticide contaminations, variable soil conditions, challenging labor markets, and the difficulty of managing quality from harvest through drying and storage without consistent infrastructure.

WHAT FARMERS MANAGE

(Similar to those of wild harvesters)

- Correct identification and proper harvesting time (sometimes seeds can be incorrect)
- Documentation and traceability
- Ensure soil is free of heavy metals and other potential contamination
- Manage weeds to minimize/prevent accidental adulteration of other species
- Microbial contamination — managed through harvest and post-harvest handling
- Physical hazards — extraneous matter
- Adulteration — depending on farming practices and weed management, location, neighboring practices
- Post-harvest handling (storing, packaging, drying, etc.)

DEEPER QUALITY QUESTIONS

- 1.Monoculture or polyculture? What are the impacts of farming practices on plant quality, soil health, biodiversity, and farmer health?
- 2.What farming practices exist when there's no organic certification?
- 3.How are farmworkers treated and paid?



Herbs drying in Bulgaria

STAGE THREE

Processor Level

Primary processing, aggregators, ingredient suppliers

Primary processing is the make-or-break stage in maintaining herb quality. It often occurs in the country where the herbs are harvested or cultivated. The fundamental goal of primary processing is rapid product stabilization through drying or extraction, followed by properly controlled storage. While these steps might seem straightforward, executing them properly requires exceptional attention to detail. The drying and storage phases are particularly vulnerable points where quality can be compromised. Even perfectly harvested herbs can be ruined during drying, storage, handling, shipping, or sterilization.

We include in this category processors, aggregators, and ingredient suppliers. Though these roles differ, broadly these are the actors who source from a number of different collectors and harvesters from different areas. In addition, they typically source different species of herbs, each with different drying and handling requirements which require a nuanced understanding of these variations.

PROCESSING STEPS TO MANAGE QUALITY

- Appropriate sampling to obtain a representative sample
- Identity testing by a valid scientific method
- Appropriate segregation of materials throughout handling
- Drying at correct temperatures to preserve active constituents
- Storage conditions that prevent mold, pests, and contamination
- Extraction using food-grade solvents where applicable. Ethylene oxide and radiological treatments are not allowed in organic production.
- Microbiological controls for pathogens. Herbs often lack the "kill step" that conventional foods have. This creates pressure for sterilization, but sterilization can impact the very quality that makes herbs valuable.
- GMP compliance throughout

CHALLENGES

Despite all controls, rejections still happen too often due to unavoidable circumstances. These quality investments represent real costs of production that need to be built into herb pricing going forward. Sometimes the material can be remediated. Other times it will be rejected. A buyer often won't have visibility into whether or not material has been remediated and they won't necessarily be told by the supplier about any remediation unless the supplier is asked. It is important to have a relationship with your suppliers so you can ask if anything is unique about the batch, whether it has been remediated and what the impacts of remediation are on the quality of the material.

ABSOLUTE REJECTIONS

Pesticide contamination — no remediation possible
Aflatoxins — cannot be removed

Identity failures — wrong genus/species
Severe mold contamination

POTENTIALLY REMEDIABLE

Heavy metals — may be partially addressed through extraction methods

Microbial contamination — sterilization/pasteurization options available

Physical contaminants — can often be removed

DEEPER QUALITY QUESTIONS

- 1.This is the stage most invisible to buyers — and the stage where quality is most often compromised. Herbs may have been dried on the roadside, contaminated by exhaust, mixed with other plant material, or any other practices to undermine their quality. None of this shows up in most standard testing.
- 2.Who are the processors? Are they invested in quality? Do they have long-term relationships with buyers, or do they simply sell to whoever offers the best price?
- 3.What is the incentive structure? When price is the only thing buyers compete on, processors are under constant pressure to cut corners.

STAGE FOUR

The Broker Layer

Most herb buyers — especially small manufacturers — buy from brokers, not directly from producers. This is often necessary and not inherently bad. Brokers can play an important role in managing the logistics of international trade and bringing value to brands or manufacturers. But the standard broker relationship is transactional: they find the price point you want, source to meet it, and protect their supplier relationships as proprietary. This again is where having a relationship with the broker is important to have visibility into the process.

QUALITY QUESTIONS

- Does the broker provide full traceability documentation?
- Can they provide Certificates of Analysis, country of origin, organic certification?
- Do they conduct their own quality testing or testing on receipt?
- Can the broker tell you the name of the farm or collection community? Will they facilitate a site visit? Will they share what they paid the producer?
- How does the broker respond when you push for more information? Resistance is data.
- Do they conduct onsite visits to their suppliers?

DEEPER QUALITY QUESTIONS

- Is your broker a partner in building a more transparent supply chain, or are they a gatekeeper that keeps the chain opaque?
- How would you know the difference?



Linden bark drying | Photo by l'Herbier du Diois

STAGE FIVE

The Manufacturer / Contract Manufacturer

Herbal products are formulated, sourced, and manufactured in many different ways. Some companies have led the way by establishing direct relationships with primary processors even while working within the traditional broker model. This level of involvement is uncommon in the industry.

Many brands instead work through contract manufacturers who manage everything from formulation and sourcing to extraction and bottling, keeping the brand as hands-off as possible. In these cases, the contract manufacturer does the sourcing through their existing supplier network — rarely disclosed to the brand, for fear the brand will go around them. The business model necessitates a focus on price rather than relationships. The herbs are typically bought and sold as a straight commodity, with quality assurance managed by the manufacturer's own internal standards. How rigorous those standards are varies enormously. Understanding the values and quality standards of the manufacturer you use is one of the most important quality decisions a brand can make.

CONVENTIONAL QUALITY QUESTIONS

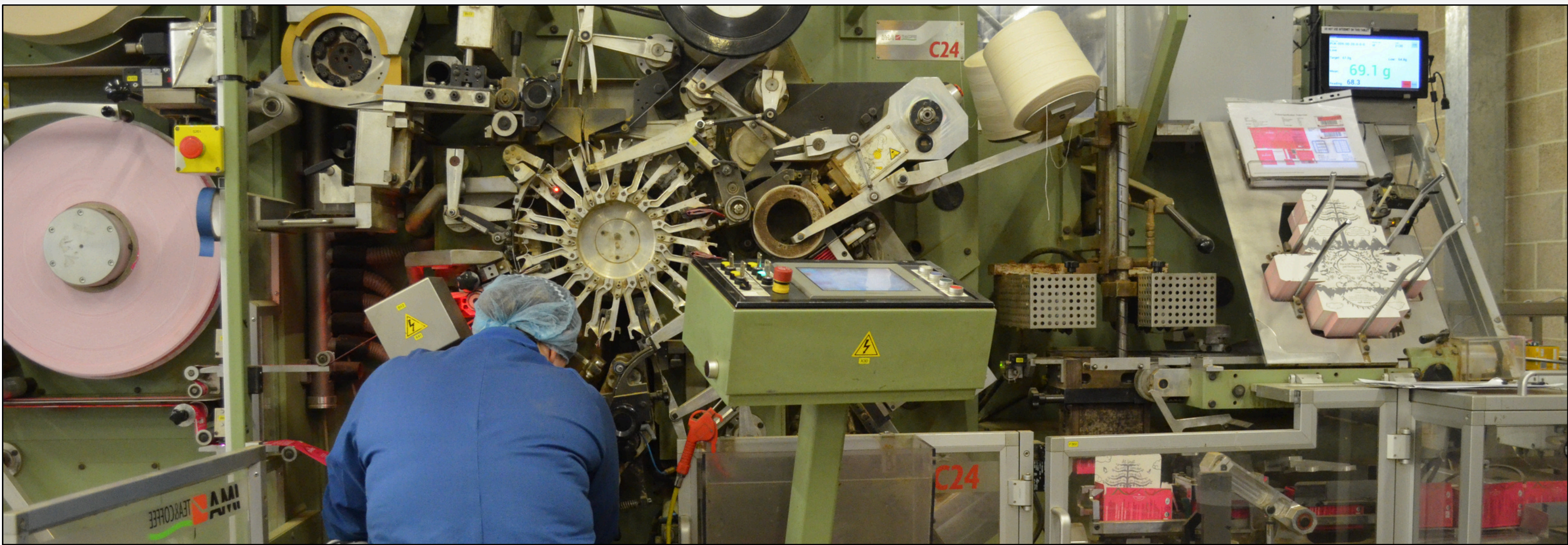
- 1.GMP compliance: documentation, SOPs, batch records, traceability.
- 2.Identity testing: organoleptic, microscopy, HPTLC, HPLC.
- 3.Purity testing: heavy metals, pesticides, microbials, aflatoxins.
- 4.Potency: constituent levels, dissolution, stability.

DEEPER QUALITY QUESTIONS

- 1.GMP compliance is a floor, not a ceiling. What does quality mean beyond compliance?
- 2.Small brands and manufacturers are often squeezed. They can't pay fair prices AND compete on price with products that don't. This is a structural problem that requires collective action.

RED FLAGS TO WATCH FOR

- Unwillingness to share specification sheets.
- Specification sheets on the manufacturer's own letterhead with no indication of origin — if you're buying a botanical, you should know where it came from and who is responsible for how it was grown, harvested, and processed.
- No in-house ingredient testing for microbials, heavy metals, or certifications. Knowing who is actually responsible for this testing is essential.
- No herbalist or botanically trained staff involved in formulation and sourcing decisions.
- The cheapest option is not often the best. Corners are being cut to bring you the lowest price. Are they corners you're willing to cut?



Tea packacking at a UK co-packer, Bristol, UK

STAGE SIX

Brands

Some brands never see the raw material or the finished products. Others are actively involved in the entire process from source to finished products and most fall somewhere in between. A brand that is actively involved in their formulation and quality assurance typically oversees the following:

QUALITY SPECIFICATIONS & TESTING

- 1. Hazard analysis required for all ingredients from farmers.
- 2. Testing required to demonstrate hazard control (testing is verification, not control itself).
- 3. Non-remediable contaminants — heavy metals, pesticides, aflatoxins (if the material fails these tests, it must be returned or disposed of).
- 4. Remediable issues — won't reject for microbial or extraneous matter, both of which can be addressed
- 5. Supplier qualification (either by a site or desk audit).

SPECIFIC QUALITY CHALLENGES

- 1. **Allergen controls** — Need proper controls for all major allergens.
- 2. **Contamination specifications**
- 3. **Identity issues** — challenging particularly with horehound/elder types where genus and species precision is critical for US regulations (though medicinally some herbs are interchangeable, commerce regulations don't accommodate herbalist perspectives).
- 4. **European sourcing complications** — mixed species lots are common unless you specifically request segregated lots.
- 5. **Certification burden** — meeting non-GMO, organic, or other certification requirements demands extensive documentation at significant cost.

REGULATORY BURDEN

- FDA inspections
- Given 15 days to address corrective actions plus implementation time
- Extensive written documentation requirements at significant expense

THE DEEPER QUESTIONS

- 1. Your name is on the label. Legally and reputationally, you own everything that happened upstream. **Does your quality program reflect that ownership?**
- 2. How has the price been determined? When you choose the lowest bid, you are making a choice about what happens at every stage above. **What does your pricing communicate to your suppliers? To your customers?**
- 3. What would it look like to use your market position to shift industry sourcing practices toward quality and transparency rather than pushing costs downward?



The Lab’s Perspective

The lab perspective is more complex than this document can address because each company can have different methods to meet their specifications. There is more detailed information on Quality Assurance and lab processes [here](#).

If material you have previously sourced doesn't pass specifications, questions to ask include:

- 1.What if anything has changed from the previous product that was tested?
- 2.Did you purchase the raw material from a different ingredient supplier?
- 3.Did the ingredient supplier purchase the material from different farmers, traders, processors than they have previously?
- 4.Did current suppliers change their farming practices?



Checking botanical identity against a Herbarium | photo by Pebani

STAGE SEVEN

The Herbalist and End User

The herbalist and end user often has little visibility into the quality of the products yet they have a unique position: they are the bridge between the supply chain and the client. They are the last person with real agency before the herb is consumed. Their recommendation carries authority. When they recommend a product, patients trust that recommendation. That authority can be used to drive demand for better-sourced products.

This [Buyer's Guide](#) produced by the Sustainable Herbs Initiative and the Institute of Natural Medicine outlines questions to ask. Below are a few general points.

THE CONVENTIONAL QUALITY QUESTIONS

- 1.Does this product work? Is it potent enough?
- 2.Is it safe?
- 3.Is it ethically sourced? (Often this means: does the label say certified organic or Fair Trade?)

THE DEEPER QUESTIONS

- 1.Energetics, harvesting conditions, intention: If you believe that these factors impact the quality of the finished herbal product, what do you know about the conditions under which the herbs you recommend are harvested? What about the intentions of the growers, harvesters and processors? Read [Following the Herbal Harvest](#) to learn more about why this matters.
- 2.Clients increasingly want to know the story of what they're taking. Practitioners can tell that story — but only if they know it themselves.
- 3.You teach patients about the healing power of relationships with plants. Are you in relationship with the value chain that provides your plants? What would it take to be?

Quality is only as strong as the relationships and economic realities at each link. Building these relationships across all seven stages — from plant to end user — is the work this toolkit invites us into.

SHI QUALITY & SUSTAINABILITY WORKING GROUP

