

Step by Step

A 7-step approach to establishing a critical path for your project management and defining the roles of marketing and R&D. **BY JOHN GARRUTO**

*"You like potato and I like pot-ahto
You like tomato and I like tom-ahto
Potato, pot-ahto, tomato, tom-ahto.
Let's call the whole thing off."*

—George and Ira Gershwin, *Shall We Dance* (1937)

The alliance of marketing and R&D certainly can be thought of as a dance, albeit sometimes as awkward as those first movements at a high school prom. The marketing and R&D functions of any company are unique unto themselves, yet considerably co-reliant as well. Furthermore, the efforts of each team are essential in bringing new products to successful launch in the marketplace. Nevertheless, while the Utopian may see their roles as symbiotic, the pragmatist often will characterize their relationship as frequently adversarial. The reality, of course, is that this collaboration is crucial to the development and introduction of safe, stable and efficacious products. Consequently, while the rewards are abundant, the process is designed to test the patience, communication and organizational skills of all participants.

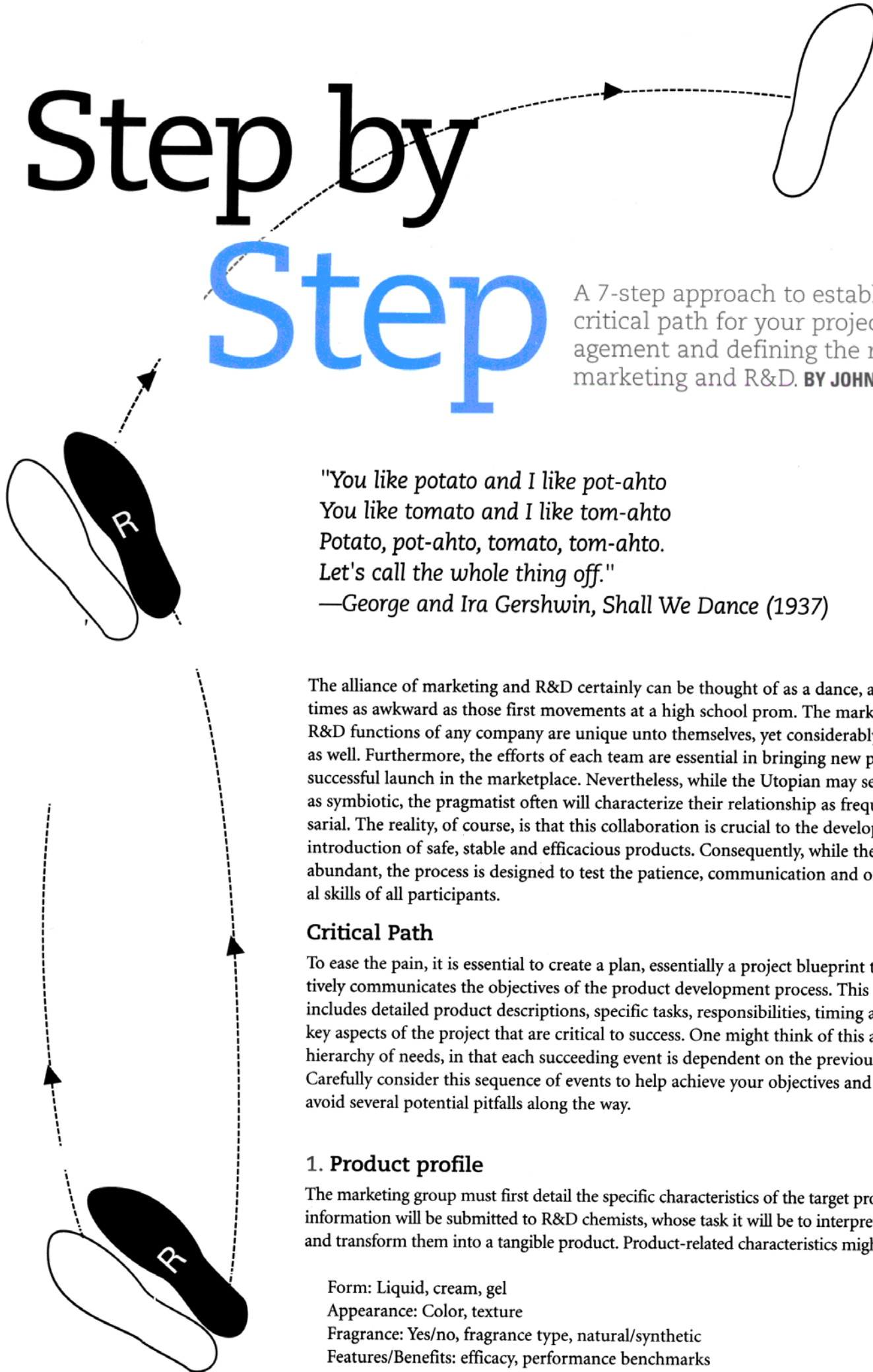
Critical Path

To ease the pain, it is essential to create a plan, essentially a project blueprint that effectively communicates the objectives of the product development process. This usually includes detailed product descriptions, specific tasks, responsibilities, timing and other key aspects of the project that are critical to success. One might think of this as a project hierarchy of needs, in that each succeeding event is dependent on the previous action. Carefully consider this sequence of events to help achieve your objectives and also to avoid several potential pitfalls along the way.

1. Product profile

The marketing group must first detail the specific characteristics of the target product. The information will be submitted to R&D chemists, whose task it will be to interpret the criteria and transform them into a tangible product. Product-related characteristics might include:

- Form: Liquid, cream, gel
- Appearance: Color, texture
- Fragrance: Yes/no, fragrance type, natural/synthetic
- Features/Benefits: efficacy, performance benchmarks
- Directions: How the product will be used



THE BASIC CRITICAL PATH

- 1 Establish a product profile
- 2 Research the formulation
- 3 Development a prototype
- 4 Evaluate/approve prototype
- 5 Conduct stability/safety testing and claims substantia-

Product claims: Specific function, advertising claims

Ingredient story: Necessary key/active ingredients, what to avoid

Competition: Where to emulate, where to differ

Cost/Price: Product cost, retail price

Geography: Where the product will be sold, climate, language, regulations

Special Requirements: Government regulations, patent issues

In addition, the intended package often will dictate the product form, viscosity, rheology and ingredient selection. Not knowing the packaging is a common mistake that will cost you down the road. Important packaging characteristics to identify include:

Container size: Ounces, grams, milliliters

Container form: Bottle, jar, tube

Container material: HDPE, PVC, PET, PP

Container dimensions/shape: Oval, square, cylindrical

Closure type: Cap, dispensing cap, pump, sprayer, foamer

Closure material: PP, urea, styrene

Orifice size: Dispensing cap, applicator, sprayer

Graphics: Label, lithographic, silk-screen

2. Formulation research

If there is agreement on the product requirements, the R&D department can begin the task of basic formula design based on the profile submitted by marketing. The basic steps in this procedure may include:

Establish formulation parameters: A strategy according to product profile

Review secondary references: Literature search, journals, trade publications

Set practical targets: What is possible, what is not

Select ingredients: Select required ingredients and vehicle components

Regulatory considerations: Global regulations, patent issues

Production considerations: Available expertise, equipment

"Dry lab" formulation: Basic starting point

When the R&D department has completed the principal research and developed an initial formula, ingredient declaration should be submitted to marketing for consideration and adherence to the product profile and its philosophy. All ingredients also should comply with cosmetic and drug regulations for each country where the product is going to be marketed and sold to avoid misunderstandings and prevent unnecessary delays and increased costs later.

3. Prototype development

Once the marketing department has given a "thumbs-up" to the initial ingredient selection and formulating strategy, the first prototype can be developed—a process of trial and error.

During this phase, the chemists or R&D group should test the fundamental functionality of the prototype, including a cursory "safety evaluation." There should be reasonable assurance that the prototype is compatible with the container materials chosen and that the product will pass stability testing with only minor modifications. A general stability evaluation can and should be performed throughout the R&D process to assure that there are no "surprises" as the project progresses.

4. Prototype evaluation

Samples of the prototype can be submitted to marketing for evaluation and comment after the chemists or R&D group has completed the initial development. The prototypes usually is reviewed by an in-house team that evaluates for sensory targets such as visual, odor and feel, as well as for performance and adherence to the target as described in the product profile. If the prototype does not meet all of the criteria, R&D will make the necessary modifications and resubmit samples for testing. If the prototype is generally well received, the marketing department may expand the product testing to a larger group within the company or to an outside panel of product evaluators or focus group. Once the formula is approved by marketing, the raw material cost of the formula is calculated and restated once more before beginning product testing.

5. Product testing

Product testing usually involves a combination of in-house and off-site testing, and should include stability testing of the product in laboratory glass packaging as well as final product packaging, to establish whether R&D has adhered to target and met marketing's criteria. The physical stability testing most often will be carried out for a minimum of 90 days and usually will include low temperature, room temperature and elevated temperature analysis as well as freeze/thaw cycle testing. Many established criteria are evaluated and usually include parameters of appearance color, odor, pH, viscosity, specific gravity and percent solids/weight loss. These criteria also may include testing for active substances if the product is considered an OTC drug, such as a sunscreen, antiperspirant and acne preparation. In addition, a Preservative Effectiveness Test (PET) is performed. Performance claims made on the package or in product advertising also will need to be substantiated.

When all groups are confident that all stability/efficacy testing is well in hand and that no further formula modifications are likely, safety testing should begin. This may include human Repeat

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Insult Patch Testing (RIPT), controlled use study and possibly an in-vitro protocol for eye irritation or other criteria. The formula will receive final approval after all testing is deemed complete and satisfactory to all departments. At this point, all product copy, including ingredients, claims, directions and label warnings, if needed, should have been approved.

6. Scale-up and manufacturing

A copy of the product formula and complete bill of materials is given to the manufacturing department or contract manufacturer. The formula will be used to develop a manufacturing batch document that will detail the qualitative and quantitative aspects of the product, as well as the required manufacturing equipment, batching procedure and other relevant information necessary to manufacture the item successfully. This also will include any relevant processing conditions with respect to temperature, mixing speed and any filling protocol, including fill weights, labeling, cap torque and batch coding requirements. The complete product specifications and quality testing parameters also should be detailed, as well as a description of the product release procedure. If the product is to be manufactured off-site by a contract manufacturer, a lab batch should be made by the contract manufacturer and approved by R&D and marketing. At this point, a pilot test batch is usually manufactured in order to work out the details of the manufacturing process in a real world environment. All information relevant to manufacturing equipment and procedures used should be documented, updated and kept with the master batch record. Once this pilot batch is successfully manufactured, tested and released, a full size production batch is scheduled. In the case of very small production requirements, the pilot batch will serve as the full manufacturing requirement. When the product is released, it is ready to ship to the marketplace and the fruits of your labor are soon to be realized.

7. Sales

The most notable achievement of a product launch is certainly embodied in the fulfillment of sales goals and commercial success. While there is no guarantee of this outcome in a fiercely competitive environment, you can certainly tilt the scale in your favor with careful planning and exceptional teamwork. This often means that each step in the process is detailed with a critical path of our own design and agreement.

Systematic Preparation

It is vital that you move through the product development process in a well-planned, systematic manner, while continuing to maintain a dialog with all departments involved. Nothing should be left to chance and there should always be sufficient time built into the schedule to allow for the invariable contingency that will often occur at exactly the wrong time. There is an ancient African proverb that says "Never test the depth of the river with both feet." Be prepared, be organized, be cooperative and you will be successful. ■ GCI

John Garruto is the founder and president of Free Radical Technology, a technical consulting firm in Oceanside, California. He has worked as a chemist and technical consultant to the personal care industry for 28 years. His firm specializes in the formulation of skin care, hair care, OTC formulations and spa and treatment products. Garruto also is past chairman of the California Chapter of the SCC and a frequent lecturer in the beauty industry.