Production Requirements Overview

This section of the toolkit contains a description of the requirements necessary for local manufacturing of CycleBeads. It is intended for program managers or other individuals who wish to better understand what local production entails, either because they are considering this option, or because they have already decided that local production will be the supply method for their country or region.

Production requirements can be broken down into five categories: (1) CycleBeads production; (2) complete production (CycleBeads with instructional insert, calendar, and primary packaging); (3) quality assurance and quality control; (4) distribution (covered in the previous section); and (5) management. Further information with regard to product specifications, detailed production guidelines, detailed QC procedures, and a hazard analysis are found in the CycleBeads Manufacturing section. That section is especially useful for component suppliers and manufacturers of the product.

CycleBeads Production

The initial production of CycleBeads (tool only) may require significant due diligence to identify capable, reputable manufacturers to make the different components (see Appendix E, Due Diligence: An Introduction and Key Questions to Ask). A program may need to identify different manufacturing facilities to make molds, produce and/or outsource components, assemble CycleBeads, and manage quality control. Furthermore, CycleBeads prototypes need to be inspected and approved by Cycle Technologies before full-scale production is started. Each of these operations is outlined in more detail below. Individual contractors or partners are responsible for ensuring that their facility is available at the time of CycleBeads manufacturing. Furthermore, the contractor or manufacturing partner is responsible for aligning production timelines and quantities among the different manufacturers to ensure timely delivery. Failure to adhere to established timelines can result in product stockouts and subsequent unplanned pregnancies.

Development of Molds

Molds for the bead and clasp components will need to be fabricated. Detailed information on the part specifications is found in the Product Specifications section. The contractor or partner will need to work with the molder to determine the correct type of mold to balance mold cost with the quantities produced. The current two smaller-scale manufacturers with which Cycle Technologies is working are using teardrop bead molds with between 10 and 44 cavities (creating 10 to 44 beads each time the mold is used). However, because molding the clasp components requires mold automation (unscrewing the portion of the mold that creates the threads), the current manufacturers are using single-cavity molds for the clasp component.

Component Manufacture

Each component (beads, clasp, string, o-ring) needs to be either manufactured or obtained through outsourcing. Local manufacturing entails purchasing of raw materials, hiring and managing production and QC staff, stocking components in sufficient quantity and ratios, and maintaining equipment.
Figure 6. Overview of production requirements

- Legal agreements with Cycle Technologies
- Engineering consultant
- Identification and agreements with component and material manufacturers

Production
- Manage production personnel
- Manage production versus demand

Mold and facilities development and Develop instructions and calendar

Component manufacture and Outsourcing components

Customs management

Assembly of CycleBeads

Cycle Technologies approval of quality

(flowchart continues on next page)
Quality Assurance and Quality Control

- QA and QC management
- Audits and inspections
- QC records and document management

Quality assurance process development

Quality control during assembly and packaging

Random sampling and lot rejection

Internal and external audits

Distribution

- Production order management
- Bookkeeping
- Registration of CycleBeads

Inventory control

Warehousing

Distribution

Customs management
Outsourcing Components

While custom beads and clasp components may be manufactured locally, manufacturing partners who choose to produce CycleBeads may find that it is more cost-effective to purchase the o-ring and string components from a domestic or international supplier. Manufacturing partners need to work with suppliers to establish lead times for delivery, component availability, and pricing sensitivity to quantity. In order to ensure supply, multiple suppliers may need to be engaged, and this can affect quantity per order and complexity of management.

Customs Management

As noted above, some components may be more cost-effective to obtain from an international supplier. Manufacturing partners should be prepared to manage import license and international customs costs, additional brokerage and duty costs, and foreign exchange logistics.

CycleBeads Assembly

After component manufacture, CycleBeads must be correctly strung and assembled. In current manufacturing settings, between 5 and 30 assemblers are employed to manually string the beads and clasp, tie the string, add the o-ring, and check the accuracy of the assembly. Because assembly is a manual process, it is often the most time-consuming and rate-limiting step to production. Currently, assembly per necklace can require up to 20 minutes of time. For manufacturing partners who choose to import CycleBeads components and assemble them locally, instructions can be found in the CycleBeads Assembly section.

Inventory Control

The manufacturing partner’s inventory system will need to include raw materials (e.g., plastic resin) and individual components (e.g., string and beads) in order to plan for assembly and final CycleBeads product. Depending on the manufacturing partner’s manufacturing arrangements, multiple inventories at multiple manufacturers may need to be maintained (e.g., number of beads at a bead manufacturer, number of instructional inserts at the printer or warehouse).

Cycle Technologies’ Approval of Quality

To ensure a high-quality product, CycleBeads necklace prototypes need to be inspected and approved by Cycle Technologies before production begins. Manufacturing partners must establish open lines of communication with Cycle Technologies including emailing product specifications and digital photographs of product articles and sending prototypes for review and comment. This review helps ensure that all CycleBeads meet production standards and minimizes the risk of unplanned pregnancies due to product failure. It also ensures that programs are in compliance with international intellectual property laws. Furthermore, Cycle Technologies reserves the right to periodically monitor and audit production quality and facilities without prior notice.
Complete Product Production
(CycleBeads plus instructional insert, calendar, and packaging)

In addition to manufacturing CycleBeads, creation or modification of accompanying materials (the instructional insert, the calendar, and packaging) also requires dedication, management, and coordination. Aligning production timelines and quantities among the different suppliers to ensure delivery per an agreed upon timeline is essential.

Instructional Insert and Calendar

Cycle Technologies provides a model instructional insert and calendar for use with the CycleBeads product. The instructional insert is available in English, French, and Spanish. IRH can also share prototypes developed in other languages. At the time this toolkit was prepared, Portuguese, Hindi, Amharic, Romanian, Albanian, Kiswahili, and Kinyarwandian versions were available. IRH also has prototype instructions developed for low-literacy audiences available. Depending on the country of use, programs may decide to translate the instructions and calendar into an appropriate local language. Programs should contact IRH to obtain samples of prototype materials in various languages.

Additionally, if the program decides that the currently available standard or low-literacy instructions are not appropriate for their country or region, they may choose to modify existing or develop new instructional inserts. Programs choosing this option will need to:

1. Request permission from IRH to use the CycleBeads name and logo. This is highly recommended because the CycleBeads name is widely included in guidance and other materials. Also, it is important to conform to US and international intellectual property laws.
2. Draft the instructional insert using an appropriate language and literacy level.
3. Submit the instructional insert to IRH for preliminary review.
4. Test the instructional insert with the local target audience.
5. Make revisions based on IRH and audience reviews.
6. Submit to IRH for final review prior to printing.

Target Audience Testing

In order to ensure the comprehension of the instructions, target field audience testing must be conducted with the instructional insert (if modified from the standard IRH insert). IRH has field testing guidelines available, and programs should contact IRH for further information and guidance.

Printing

Printing of instructional inserts and calendars for inclusion with the CycleBeads product is typically outsourced to a dedicated printing company. Depending on the complexity of the design, printers may need to produce four- to eight-color prints with a sufficient degree of quality to ensure legibility. Some countries have chosen to use black-and-white versions. Manufacturing partners are responsible for developing the original camera-ready art work, contracting with printers and establishing quotes and contracts, evaluating and approving proofs, evaluating and approving first-print articles, and contracting for printing and folding at desired quantities per an established timetable. Because
of the lowered costs for higher volumes, the manufacturing partner may need to establish an appropriate storage facility to store the instructions and calendars until they are needed for inclusion with the CycleBeads products.

**Packaging Sourcing**

Manufacturing partners will be responsible for obtaining individual packages, boxes for stand-alone retail sales (if applicable), and shipping cartons or containers. Currently produced CycleBeads are packaged in a clear plastic bag that contains the CycleBeads, instructions, calendars, and an extra o-ring. Programs and manufacturing partners interested in changing the primary packaging or retail boxes should contact Cycle Technologies for guidelines, electronic files of existing materials if appropriate, and permission to use the CycleBeads name and logo.

Programs and manufacturing partners will also need to procure multiunit cartons for shipment of the CycleBeads product from the manufacturing partner or assembly site to the point of use. Carton size should be matched to the needs of the facilities that will be selling and distributing the CycleBeads product.

**Packaging and Cartoning**

After manufacturing of all the product components, the CycleBeads need to be packaged and cartoned. Packaging can occur at the same time and location as product production (after the CycleBeads are assembled, they can be packaged immediately). Or packaging can be delayed or performed at a different site. As noted below in the section on Quality Assurance and Quality Control, the point of packaging is typically another opportunity to evaluate the quality of the CycleBeads product.

**Shipping**

Programs should check local shipping regulations, as sometimes shipping taxes vary depending on the number of units shipped per carton within a country. Cycle Technologies ships materials in cartons that contain a standard quantity of units (usually 500 units).

**Quality Assurance and Quality Control**

Quality control (QC) and quality assurance (QA) are crucial components of the manufacturing process. They ensure the CycleBeads product is consistently of high quality. This increases user confidence in the product and the continued success of the SDM by ensuring that unplanned pregnancies do not occur as a result of preventable defects to the CycleBeads product.

**Quality Control During Assembly and Packaging**

As outlined in the Quality Assurance and Quality Control section under CycleBeads Manufacturing, QC (the operational techniques and activities that are used to satisfy quality requirements) is required during receipt of components, and assembly and packaging of CycleBeads. QC at these stages in manufacturing will reduce the number of nonconformities (defects) in the final product and reduce the incidence of rejected lots (such as lots that cannot be distributed because of quality problems). QC requires dedicated personnel, and because 100 percent inspection is performed, allotment for sufficient time during the manufacturing process is required.
Figure 7. Overview of quality assurance processes

### Quality Assurance Process Development

QA processes are a set of management or process activities that demonstrate that the manufacturer meets established quality requirements. These activities can include quality standards development, reporting standards, auditing standards, and protocols. The QA processes comprise a written plan that outlines all the steps taken to ensure the quality of the product.

QA processes will need to be established to ensure the quality of each component and the overall product. Some materials used to develop these processes are given in the Quality Assurance and Quality Control section of this toolkit, but each manufacturing partner will need to establish QA processes that are appropriate for their site and production scenario.

### Quality Control Records and Document Management

As part of QA, processes for recording QC results and managing, storing, and distributing these results must be established. Manufacturing partners are responsible for ensuring quality products and demonstrating this quality to Cycle Technologies. QC documents should be detailed, kept current, and periodically audited for completeness and quality.

### Random Sampling and Lot Rejection

As outlined in the Quality Assurance and Quality Control section, agreements with Cycle Technologies will require random product sampling of each production lot.
Examples of third-party QC firms include Bureau Veritas, Intertek, and SGS. (Note that Cycle Technologies does not specifically endorse any of these firms.) Based on the results of this sampling and the established quality standards, final lots may be rejected. Rejection of the lot may require disposing of the lot or reestablishment of 100 percent inspection for the entire lot. QC at assembly and packaging can reduce the number of rejected lots, but manufacturing partners must budget both time and funds for the disposition of rejected lots.

**Internal and External Audits**

Manufacturing partners are expected to conduct periodic quality audits to ensure the current quality of the CycleBeads product. To help ensure freedom from bias, these audits should be conducted by personnel not directly involved in production and should be extensively documented separately from in-process QC records. Additionally, every production lot is subject to random sampling and inspection by external auditors, as is standard industry practice. See Appendix F for a sample third-party quality control inspection.

**Management**

There are many managerial tasks involved in the manufacturing and distribution of CycleBeads.

**Legal Agreements With Cycle Technologies**

Before moving forward with local production, a manufacturing partner must sign a product manufacturing and distribution agreement with Cycle Technologies. This assures Cycle Technologies that the product will be made in a high-quality manner, so as not to damage the product image and to prevent unplanned pregnancies that could result from product failure (see Hazard Analysis, Appendix D). The agreement allows the manufacturing partner to legally manufacture the product in a certain country or region.

**Identification of and Agreements With Component and Material Manufacturers**

Partners engaged in CycleBeads manufacturing will need to research, identify, and establish working relationships with component and material suppliers. (For more information on how to investigate a potential collaborator, see Appendix E, Due Diligence: An Introduction and Key Questions to Ask). In order to obtain the best quality and the lowest prices, materials sourcing may require domestic or international agreements (or both). In order to avoid relying on a single (and possibly unreliable) source for a required material or component, manufacturing partners may need to have multiple suppliers for each material. Component and materials procurement schedules must also be coordinated with manufacturing schedules.

**Production Versus Demand Management**

Local production must be managed in relation to the in-country demand (see the section on Estimating Demand under Determining How to Supply CycleBeads.) Manufacturing partners are responsible for maintaining an adequate supply of CycleBeads to promptly fill orders. However, in order to avoid costly unsustainable backlogs, they should not stockpile more than a 12 month supply of CycleBeads in storage at any one time unless a different arrangement has been negotiated with Cycle Technologies.
Manufacturing partners should balance these restrictions with economies of scale and the cost reductions that typically accompany increasing volumes of manufacture.

**Engineering Consultant**

Programs will need to engage an engineering consultant or consulting firm in order to identify, evaluate, and assist with management of manufacturing operations. Consultants should be chosen who have previous experience in molding plastic consumer goods and who have previously worked in the specific country or region. The consultant’s activities should include:

- Identifying appropriate local manufacturers and vendors.
- Reviewing technical requirements for CycleBeads production with manufacturing partners.
- Assisting with obtaining and reviewing business references for manufacturing partners.
- Assisting with inspection of manufacturing facilities to determine if business practices meet manufacturing requirements.
- Assisting with final selection of a manufacturing partner.
- Assisting with negotiating and finalizing contracts with manufacturing partners and vendors.
- Assisting with initiation of manufacturing, operation troubleshooting, and inspection of first articles.
- Assisting with establishing appropriate QC measures.
- Assisting with technical communications between the manufacturing partner and Cycle Technologies.

**Production Personnel Management**

The manufacturing partner will also need to ensure proper management of personnel in charge of production. Depending on the production arrangement, there may be multiple groups responsible for individual aspects of the final product (component manufacture, assembly, instructional pamphlets, and packaging). Proper management of multiple parties will include:

- Detailed scheduling of activities.
- Maintenance of stock or carefully arranged coordination of component manufacture.
- Assurance of payments (salaries, raw materials, components, facilities, and shipping).

Additionally, the manufacturing partner is responsible for ensuring that it complies with all applicable laws and regulations pertaining to wages, overtime compensation, benefits, hours, hiring and employment, workplace conditions and safety, the environment, collective bargaining, and freedom of association.

**Quality Assurance and Quality Control Management**

The manufacturing partner will need to manage all QA and QC activities. The manufacturing partner will need to implement QC measures under International Organization for Standardization (ISO) guidelines to ensure that no defective product is shipped to any distribution agent. The manufacturing partner will also need to manage periodic audits by Cycle Technologies or a third-party representative.
Additionally, the manufacturing partner must immediately repair or replace any defective product at its own expense regardless of the manner in which the defect was reported. The manufacturing partner should also be capable of managing public relations issues raised by problems of product quality.

**Bookkeeping**

The manufacturing partner must be capable of providing a production report including:

- Past production quantities—quantities produced in previous months/years (including trend data, if available).
- Current inventory—CycleBeads product stock in inventory including itemization of component parts before assembly.
- Current year-to-date production quantities.
- Distribution performance—distribution locations, order lead times, and quality problems.
- Forecasting for future production quantities (annual and monthly).

**Audits and Inspections**

Each production lot of CycleBeads must be inspected, and its quality is also subject to external review by representatives or appointees of Cycle Technologies which reserves the right to audit, without notice.