Bio-OS: Standardized Cell Manufacturing Infrastructure for PRINT-Scale Bioprinting

Supporting the ARPA-H PRINT Mission

The **ARPA-H PRINT program** challenges teams to move beyond proof-of-concept bioprinting toward *universally matched, on-demand organ manufacturing*. Achieving this vision requires not only advances in printing technologies, but also a robust, scalable, and reproducible approach to cell sourcing and expansion that can operate continuously from discovery through translation.

Ronawk's Bio-OS platform was developed to address this exact gap.

The Cell Manufacturing Challenge at PRINT Scale

PRINT teams commonly encounter a set of structural risks as programs mature:

- Progressive **cell senescence and phenotype drift** during repeated expansion
- **Batch-to-batch variability** across long, multi-phase programs
- High **cost and operational burden** associated with plasticware, media, labor, and space
- Discontinuities between **R&D-scale workflows and translational or GMP pathways**
- Reliance on expert-dependent processes that are difficult to standardize or transfer

These challenges often emerge not during early feasibility studies, but during scale-up, integration, and transition points, precisely where PRINT programs must succeed.

Bio-OS: Infrastructure for Continuous, Scalable Cell Expansion

Bio-OS is a standardized biological operating system built around Ronawk's Bio-Blocks, designed to support continuous cell expansion using the same physical and biological microenvironment from early research through production.

Key attributes relevant to PRINT programs include:

- **Continuity across scales**
  A single substrate and culture environment from R&D through manufacturing, reducing biological discontinuities.
- **Reduced senescence and phenotype drift**
  Cells expand without repeated subculture stress, supporting longer productive lifetimes and more stable biological outputs.
- **Improved reproducibility**
  Standardized microenvironments enable consistent cell behavior across batches, operators, and sites.

- **Lower operational burden**
  Reduced media consumption, labor, consumables, and footprint compared to conventional approaches.
- **Primary-source compatibility**
  Designed to support expansion directly from primary cells without forcing early, irreversible process decisions.

Why Bio-OS Matters for PRINT

Bio-OS does not replace bioprinters or tissue-specific differentiation strategies. Instead, it provides **foundational infrastructure** that allows PRINT teams to:

- De-risk cell supply as programs scale
- Maintain biological fidelity over extended timelines
- Simplify tech transfer and manufacturing transitions
- Focus innovation effort on organ design and function, not cell expansion logistics

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Validation and Readiness

Ronawk has generated comparative data evaluating stem cell expansion across conventional 2D systems, spheroids, Matrigel-based cultures, and Bio-Blocks, demonstrating improved stability and scalability. The platform is actively used with CROs and CDMOs facing translational-scale cell manufacturing challenges.

Engagement Model

Ronawk engages as an **enabling infrastructure partner**, offering early technical discussions, data review, and pilot exploration without requiring changes to a team's core scientific approach.

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