

**Milestones**

2008

**CATALOG AND PRICE LIST FOR  
GOVERNMENT BUYERS**

Milestones | the critical thinking company



GSA Contract Number: **GS-10F-0178U**  
GSA Contract End Date: 26 March 2013  
MOBIS 874-1 Consulting Services  
MOBIS 874 1RC Disaster Recovery  
Woman-Owned, Small Business Concern

# Milestones

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## CONTACTS FOR QUESTIONS AND PURCHASING

### **Milestones | the critical thinking company**

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# Milestones

## CONTRACTING VEHICLES

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## NAICS CODES

### **541611 Business management consulting services**

Milestones provides operating advice and assistance to governmental organizations, businesses and other organizations on administrative management issues, such as business process improvement, strategic and organizational planning and transition (commercialization) planning and implementation.

## LABOR CATEGORY AND RATE

### **Labor category**

Commercial Job Title: Executive Consultant

#### *Minimum/General Experience*

- Core competencies
  - 10 years of experience in the senior management and commercialization of advanced medical technologies.
  - Experience providing business process improvement/refinement consulting and guidance.
  - Candidate must have demonstrated experience with P&L (profit and loss), creation/management and leading development staff.

*Functional responsibility:* Executive consultant performs competitive US government new business development; process/program improvement consulting and program management of complex commercial and US Government contracts with attention to adherence to budget and program refocus as needed.

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*Minimum education:* Bachelor's degree.

## Rate

Executive Consultant awarded MOBIS rate: \$235.76 per hour

A subject matter expert who performs complex business case analysis, research planning and implementation, documentation work with articulated findings and recommendations. Work requires the highest degree of fluid thinking, roadblocks identification and resolution using creativity and interpersonal strengths, independent judgment and decorum when briefing command staff. The executive consultant has the ability to expertly and with intellectual integrity integrate critical thinking and objective perspective in the performance of tasks and drill down on those that present insights and possible solutions to the tasks at hand. The executive consultant coordinates project tasks and is capable of integrating conceptual thinking into tangible solutions.

## WHAT WE DO

Milestones | the critical thinking company provides commercial assistance to government program managers who are engaged in (1) the research and development of *pre-commercial* products that have the potential to address requirements and resolve gaps, and (2) the evaluation and specification of *commercial* products available through COTS procurement.

Program managers and their teams are adept at providing technical review of technologies and products. However, products that pass technical review may bring with them unresolved technology and business risks. Left unaddressed these risks could complicate and perhaps compromise procurement and the ability of an organization to deliver on mission and goals.

Government buyers retain the analytic services of Milestones because we bring critical thinking and objective perspective to our clients and the mission critical and often time sensitive challenges they face.

# Milestones

## SERVICE OFFERINGS FOR GOVERNMENT BUYERS

Offered under **GSA MOBIS 874-1 Consulting Services and MOBIS 874 1RC Disaster Recovery**

**A. Commercial Potential Analysis** using Milestones' proprietary methodologies, Product Assessment and Commercialization of Technologies (**PACT**) and the Essential Elements for the Commercialization of Technologies (**EECT**). PACT and EECT are performed for a variety of purposes, e.g., technology and business risk evaluation of grantees for government funding and evaluation of grantee proposals for technology portfolio "fit." A Commercial Potential Analysis report is typically performed alongside *technical* review of grantee proposals. The report is organized as follows: Company Overview; Opportunity/Need for Proposed Products; Market Evaluation; Price and Competition, Management; Business Model; Finance; Intellectual Property Review; Product Development Review and Marketplace Relevance; Manufacturing Strategy; Regulatory Strategy and Technology and Business Risk Assessments. The rationale for Commercial Potential Analysis is to correlate and bridge requirements, gaps and support organizational mission with technology and business risk.

**SEE WORK EXPERIENCES** 1, 2, 3, 4, 5; and 8 on pages 8 - 10

**B. Know-your-customer end-user needs assessment** is typically performed at one or more stages in the technology development process, e.g., product design, R&D, manufacture, product launch and next generation product development. This activity audits product relevancy and desirability by end users and provides a foundation for product success. End-user needs assessment is highly regarded by government buyers, prospective investors and marketing partners with access to dual use markets and regulatory authorities. *Knowing the market* can reduce risk for critical partners essential to the transition of developmental stage technologies to commercial markets.

**SEE WORK EXPERIENCE** 6 on page 10.

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- C.** Milestones performs **Special Studies and Analysis** when the project calls for in-depth understanding of circumstances or conditions that have the potential to significantly affect the subject under study. These circumstances typically signal institutional “big change” and bring about cycles of willingness to integrate or provoke unwillingness to integrate change prior to acceptance and adoption. A good example of these circumstances include “disruptive technologies” and products that fundamentally can change the basis of competition in an industry sector. They need to be gathered, codified and understood to facilitate acceptance and adoption among constituents important to the development process.  
**SEE WORK EXPERIENCES** 6, 7 on page 10
- D.** Milestones provides **Commercial assistance** to grantees that have received government awards and grants, e.g., SBIR, STTR, congressional directed funds, or through broad agency announcement programs (BAA). Commercial assistance can range from evaluation of a grantee’s intellectual property (IP) portfolio leading to an IP strategy, to evaluation of a regulatory strategy, pricing/reimbursement strategy, and the attainment of “auctionable” milestones that when achieved increase the value of a grantee’s organization. Commercial assistance can also provide a tangible and desirable exit strategy for inventors who wish to remain in their current professional venues, e.g., academia, and military laboratory.  
**SEE WORK EXPERIENCES** 1, 3, 4 , 5; and 8 on pages 8 - 11
- E. Market Analysis.** Please refer to “Work Experience” items **A, B, C** immediately above.
- F.** In support of COTS purchasing, contribute to a procurement activity additional **business indices**, e.g., competition, partnerships, patents and licenses, regulatory strategy and review of financial community analysts’ reports and work with procurement specialists to integrate technical and business risk assessment into purchasing activity. This activity may provide business metric rationale for sole source procurements when product

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specifications developed by researchers and system integrators are critical and exacting.

**SEE WORK EXPERIENCE** 5 on page 10

## WORK EXPERIENCE

As tri-military service subject matter experts (SMEs), Milestones has provided commercial assistance to U.S. military organizations and subordinate activities, including repeat assignments (2002 – 2008):

- US Army Medical Research and Materiel Command, Acquisitions (USAMRMC)
- Telemedicine and Advanced Technology Research Center (TATRC), a subordinate activity to the USAMRMC
- Congressionally Directed Medical Research Programs (CDMRP), a subordinate activity to the USAMRMC
- National Medical Technology Testbed (NMTB), a grantee of TATRC
- US Air Force Surgeon General Modernization Directorate (USAF SG)
- US Navy, Naval Research Laboratory, Bethesda, MD
- 311 Medical Modernization Integration, Health Sciences Wing, a subordinate activity to USAF SG

### **US Army Medical Research and Materiel Command, Acquisitions (USAMRMC) (FY2005 – FY2007)**

- 1.** For USAMRMC, Acquisitions, Milestones **invented the Essential Elements for the Commercialization of Technologies methodology to assess commercial potential** of 17 select technologies (of 1,300) funded through congressionally directed appropriations. Following the assessment, three technologies were elevated to receive advanced development counsel, which included

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preparing grantees to meet informally with the US Food and Drug Administration in connection with development of a regulatory strategy; needs assessment for technologies to ensure the technology application meets physician/physician need; and needs assessment research among target market groups to assess clinical utility and relevance to the standard of care. **Result:** Subsequently, USAMRMC contracted the PACT team to develop a curriculum, "Essential Elements for Commercializing Technologies," to assist government program managers, advanced development personnel and contracting officers to integrate commercial potential and technology and business risk assessment into technical review processes. The curriculum has been adapted for presentation to private sector international bioscience conferences, including BIO, and military health fora. (June 2005 – February 2007)

- 2.** For the Peer Review and Medical Research Program (CDMRP), a subordinate activity to USAMRMC, Milestones worked with senior staff to develop a **presentation, "Next: Commercializing Your Technology," for the April 2004 Military Health Forum.** The target audiences were principal investigators who had received development grants from CDMRP and program managers for CDMRP. **Result:** The **thinking underlying the presentation led to the formation of the USAMRMC Product Assessment and Commercialization team.** (June 2005 – February 2007)
- 3.** For the Telemedicine and Advanced Technology Research Center (TATRC), a subordinate activity to the US Army Medical Research and Materiel Command (MRMC), **Milestones provided business case analysis** for TATRC's monthly Product Line Review (PLR) that brings together a panel of technical and technology and business risk subject matter experts to assess the status of more than 100 technologies ranging from cellular biology, to telemedicine, molecular biology, gene therapy, and tissue engineering. **Result:** After three of 18 monthly

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sessions, Milestones was the designated subject matter expert for business evaluation. (November 2003 to January 2005)

4. For the National Medical Test Bed (NMTB), a grantee of TATRC, Milestones provided **business case analysis for technologies that NMTB believed to have high commercial potential**. Milestones' subject matter expertise included: commercial potential evaluation; technology and business risk assessment; intellectual property review and would represent an asset to the inventor and subsequent investors; financial review for fundraising purposes, partnerships and product positioning and launch. **Result:** During the three-year relationship, Milestones worked with a number of emerging growth research institutions and product development-stage companies yielding five commercialized technology applications from five companies. (January 2002 – June 2004)

### US Air Force Surgeon General Modernization Office

5. Milestones provided (1) **technology and business risk assessment and (2) commercial potential analysis** for more than 60 technologies submitted by grantees seeking development funds through the Directorate's Broad Agency Announcement (BAA) program. **Result:** In addition to receiving technical review, the technologies received technology and business risk assessment and commercial potential evaluation in support of COTS procurement. (2004 – 2008)
6. Milestones **designed and implemented a comprehensive end-user needs assessment and report** (Special Studies And Analysis) in connection with gene-based diagnostics involving more than 65 interviews among a broad spectrum of constituents. Milestones evaluated the presence of market, market readiness, acceptance and willingness of end-users to integrate the new tests into the standard of care and what could be expected as cost benefit of gene-based tests that were faster, exquisitely sensitive

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and specific for the testing for infectious pathogens, but not necessarily less expensive. **Result:** Milestones determined that the acceptance and integration of gene-based tests into the standard of care would be delayed by a variety of cross constituent concerns, including physician education, the costs relative to trading out slower but largely as effective current testing. Milestones recommended caution, continued cost-benefit analysis as more tests were brought to market and to monitor who was embracing them before committing the AFMS to the new modality. (FY2006 – FY2007)

- 7.** As a member of a team, Milestones **researched and wrote the “market entry/commercialization” chapter for the Directorate’s 2008 – 2015 strategic plan** that embraced the use of gene-based diagnostics as tools of personalized medicine. **Result:** While Milestones’ learned that genetic scientists were making important discoveries that would support personalized medicine, Milestones reported that personalized medicine represented as much promise as challenge. Milestones included in its chapter a path for acceptance and integration for personalized medicine into the standard of care. (FY2007 – FY2008)
- 8.** Milestones provided **market, manufacturing and competitive analyses to assess technology solutions and market readiness** for a brain acoustic monitor (BAM) to detect traumatic brain injury (TBI), the signature injury for warfighters in Afghanistan and Iraq. **Result:** Following market, technology and manufacturers analysis, Milestones reported that the TBI monitor that had been funded by the Directorate needed to develop a comprehensive FDA regulatory strategy and clinical testing strategy without which BAM would not be approved by the FDA. Having performed a comprehensive competitive analysis of competing research and development, Milestones recommended that BAM

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developers negotiate with the FDA a clinical strategy for testing the effectiveness of the brain acoustic monitor. (FY2007 – FY2008)

9. Working closely with the RPM™ molecular diagnostic team and the Naval Research Laboratory, Milestones designed and implemented a **pre-IDE regulatory strategy and pre-IDE submission** for a molecular diagnostic platform that detects upper respiratory infections for military and civilian markets. Activities included writing an informal Investigational Device Exemption (IDE) for the EOS/ACTD (Epidemic Outbreak Surveillance/ Advanced Concept Technology Demonstration) for the RPM™ molecular diagnostic. **Result:** The pre-IDE activity established a beneficial dialogue between the Air Force, Navy and the FDA. The RPM™ molecular diagnostic development program was suspended when the specificity of the proposed medical diagnostic failed to achieve commercially relevant standards for patient care. (November 2004 to June 2005).

## WORKING WITH CLIENTS

Milestones prides itself in listening intently to the “voice of the client” and specifically addressing client requirements and working parameters. We document our discussions and present a work plan that presents a solution that is benchmarked to the client’s requirements and gaps, and factors into the solution our unique insights of our clients, their perceptions and experience. In exchange, we bring our critical thinking skills, objective perspective and subject matter expertise to the activity.

When the client feels comfortable with “fit” and the ability for us to form a team to collectively address the issue at hand, we work to develop a solution that meets their needs. We strive to engage and involve our client throughout the program period and present interim reports to provide both feedback and understanding among the parties.

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We manage budgets, timelines, works plans aggressively and forecast variances that will affect budget and timeline. Our goal is to build trust with the process and to eliminate surprises. For each client project Milestones assigns a project manager/relevant subject matter expert who is responsible for ensuring that performance expectations, budget, timeline are met or exceeded. A monthly progress report (MPR) reports:

- ☑ Monthly invoice activity
- ☑ Status of deliverables against contracted tasks
- ☑ Approved travel and trip report
- ☑ Summary of work for the current month
- ☑ Changes to the Program Management Plan and projection of variances with full explanation
- ☑ Variance with government dependencies upon which Milestones depends to do its work
- ☑ Roles and responsibilities: reporting changes in staff or suppliers and impact on the project
- ☑ Projected activities for the upcoming month
- ☑ Proactive, innovative and efficient performance by the team

The project manager reviews the MPR with the client on a monthly basis. Milestones' CFO reviews MPRs on a quarterly basis and reviews budget, timeline and performance as a quality control measure.

## EXECUTIVE CONSULTANT BIOGRAPHIES

### **Lorraine Ruff, President**

For more than two decades, Lorraine has provided counsel to the senior management and command officers of biomedical and advanced technology organizations and medical research Commands respectively, and in doing so has shaped the field of science marketing.

Lorraine merged Charlton Ruff Communications with Gabriliska Consulting in 1997. The merger resulted in Milestones | the critical thinking company.

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As a tri-service subject matter expert (SME) to branches of the U. S. military, Lorraine provides “dual-use” product assessment and commercialization counsel for technology portfolios and developmental products that have the potential to address military requirements and gaps.

In the civilian community, she works with researchers and executives to position their technologies and companies respectively on a competitive basis to reach and positively influence audiences essential to their success,

Prior to Milestones, Lorraine provided marketing science counsel to advanced technology companies located in the United States and Canada. She co-founded Chromos Molecular Systems [TSE:CHR], Vancouver, BC; positioning the corporation worldwide as the *artificial chromosome company* and was instrumental in raising CDN \$10M in seed round capital. The company completed its Initial Public Offering in summer of 2000. Lorraine is a founding director of Canton Biotechnologies, Baltimore, MD, a start-up focused on the discovery and development of novel wound healing therapies.

During her Boston years, she was practice director of the international bioscience communications division and general manager of Hill & Knowlton/New England, the world's largest public affairs firm. As general manager she directed the region's bioscience, information technologies (IT), and consumer products practices and a staff of 35. As practice director of the bioscience communications division, she led a 22-member team of marketing, business and PR practitioners and counseled CEOs of more than 50 technology and biomedical companies – from start-ups to major industry players – on a worldwide basis, supporting \$350 million in private and public financing.

At Arthur D. Little, (ADL) the international technology and management-consulting firm, Lorraine directed the repositioning of the 100-year old firm for the year-long, multi-million dollar project. Following repositioning, ADL expanded annual sales from \$180 million to over \$1 billion. Lorraine received the Arthur D. Little President's Award for program management excellence.

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Lorraine began her career as a science and technology reporter for the Portland Oregonian. She was nominated for a Pulitzer Prize for her work in environmental reporting.

Lorraine has been an adjunct professor in bioscience communications at Simmons College in Boston and guest lecturer for the U.S. Army Medical Research and Materiel Command on the Essential Elements of Commercializing Technology. Lorraine attended the University of Washington and graduated Oregon State University with a Bachelor of Science degree in Technical Journalism. [lorraine@thinkmilestones.com](mailto:lorraine@thinkmilestones.com); 253-841-2934 Direct

### **David A. Gabrilka, CEO**

David has more than 25 years' management experience in Fortune 500 and entrepreneurial companies. His expertise spans a broad spectrum with specialization in technology integration and commercialization.

As co-founder of Milestones – a business strategies and science marketing firm – David has for the last decade collaborated to build a diverse portfolio of more than 60 client relationships in drug development, diagnostics, and bioinformatics. He works with executives to develop business strategies, from technology assessment through market analysis, product development and product positioning. With his business partner, David writes news and commentary for business and life sciences publications.

As a tri-service subject matter expert (SME) to branches of the U. S. military, David provides "dual-use" product assessment and commercialization counsel to a number of military research portfolios whose research organizations and companies have received funding through congressionally directed appropriations. The tri-service technology portfolios include the U.S. Army's Medical Research and Materiel Command (MRMC) as a founding member of the Product Assessment and Commercialization Team (PACT) program, the Telemedicine and Advanced Technology Research Center (TATRC) and the Congressionally Directed Medical Research Programs (CDMRP) located at Ft. Detrick, MD. Additionally he provides

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product development counsel to the Office of the USAF Surgeon General | Directorate of Modernization (SGR) and the Naval Research Lab.

For the decade prior to Milestones, David participated in the formation and executive management of eight life science companies resulting in value creation. He consulted to a wide range of healthcare sector companies including: therapeutics; point-of-care diagnostics; microbial feed additives; biochemicals (e.g., lipids, proteins, and polysaccharides); and image processing software for medical and scientific applications. He's provided due diligence and technology evaluation in support of fundraising and other strategic initiatives for the venture capital industry.

David initiated his career at Abbott Diagnostics and through a decade managed sales and operations for the African Business Unit and hematology market development as the company evolved exponentially, from a \$100 million to a \$1 billion division. Expertise included immunodiagnosics and analytical systems. He was awarded "Salesman of the Year" at the end of his first full year at Abbott Diagnostics in 1976. Based on his performance at Abbott, David was recruited to Syntex (Syva) as International TDM Market Manager for the core international business of therapeutic drug monitoring.

He has served on the Board of Directors for Response Biomedical and Novate Technologies. David has co-authored more than 20 business articles and is frequently tapped by business writers for insights into the growth and development of the life sciences and biotechnology industry. He attended university on both football and academic scholarships and graduated the University of Wisconsin - Madison with a B.S. in Zoology.

[davegab@thinkmilestones.com](mailto:davegab@thinkmilestones.com); 206-841-0022

## ORDERING INSTRUCTIONS

If you are interested in discussing your project with Milestones consulting services through our MOBIS GSA Schedule, we are available by telephone, videoconference or in person:

# Milestones

**Lorraine Ruff, president**

lorraine@thinkmilestones.com

253.841.2934 Direct

**David A. Gabriliska, CEO**

davegab@thinkmilestones.com

206.675.0022 Direct

## TERMS AND CONDITIONS

**Special item number(s) awarded:** 874-1

**Hourly rate:** \$235.76 for Executive Consultant, please see "Labor Category and rate, page 4 -5, which appears earlier in this Catalog and Price List.

**Order size:** Maximum order: \$1,000,000; Minimum order: \$300

**Geographic coverage** (delivery area): Domestic only

**Point(s) of services performance:** Seattle, WA; client location

**Discount from list prices or statement of net price:** discounts already deducted

**Quantity discounts:** None Offered

**Prompt payment terms:** None offered

**Notification that Government purchase cards are accepted at or below the micro-purchase threshold:** Yes

**Notification whether Government purchase cards are:** Accept Over \$2,500

**Foreign items (list items by country of origin):** NA

**Time of delivery:** Specified on Task Order

**Expedited Delivery:** Contact Contractor

**Overnight and 2-day delivery:** Overnight and 2-day delivery are available.

**Urgent Requirements:** Contact Contractor

**Ordering address:** Same as company address

**Ordering procedures:** See "Ordering Instructions", page 16

**Payment address(es):** Same as company address

**Warranty provision:** Contractor s Standard Commercial Warranty

**Export packing charges, if applicable:** N/A.

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**Terms and conditions of rental, maintenance, and repair (if applicable):** N/A

**Terms and conditions of installation (if applicable):** N/A

**Terms and conditions of repair parts indicating date of parts price lists and any discounts from list prices (if applicable):** N/A

**Terms and conditions for any other services (if applicable):** N/A

**List of service and distribution points (if applicable):** N/A

**List of participating dealers (if applicable):** N/A

**Preventive maintenance (if applicable):** N/A

**Special attributes such as environmental attributes (e.g., recycled content, energy efficiency, and/or reduced pollutants):** N/A

**Section 508 compliance on Electronic and Information Technology (EIT) supplies and services:** N/A

**Data Universal Number System (DUNS) number:** GS-10F-0178U

**Central Contractor Registration:** Registered